PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: Daniel D. Ryan
P.O. BOX 26618
MILWAUKEE, WISCONSIN 53226-0618

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	30 MAR 2007
Applicant's or agent's file reference 18631-PCT	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US06/33741	29 August 2006	20 October 2005

International Patent Classification (IPC) or both national classification and IPC
IPC(8) - A61F 11/00 (2007.01)
USPC - 606/108

Applicant APTUS ENDOSYSTEMS, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US	Date of completion of this opinion	Authorized officer:
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	07 February 2007	Blaine Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/237 (cover sheet) (April 2005)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US06/33741

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into _____ , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material

      ☐ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material

      ☐ on paper

      ☐ in electronic form

   c. time of filing/furnishing

      ☐ contained in the international application as filed

      ☐ filed together with the international application in electronic form

      ☐ furnished subsequently to this Authority for the purposes of search

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US06/33741

Box No. V **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	3, 5, 6-10	YES
	Claims	1, 2, 4	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-10	NO
Industrial applicability (IA)	Claims	1-10	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1-2 and 4 lack novelty under PCT Article 33(2) as being anticipated by Heinzelman et al (US 5,364,351).

Regarding claim 1, Heinzelman et al disclose a guide device comprising a guide tube (14) defining a guide passage (see Figures 2 and 3) through which an operative tool (16) can be deployed into an interior body region, and a steering assembly (12) comprising a deflecting element (56) coupled to a distal end region of the guide tube to apply a deflecting force to bend the distal end region, an actuator (26), and a linkage system (18) coupling the actuator to the deflecting element to apply the deflecting force in response to operation of the actuator (column 3, lines 29-42), the linkage system including a rack (32) and a gear train (30) coupled to the rack, the linkage system being operative to translate rotation of the actuator into linear movement of the rack and rotation of the gear train to apply the deflecting force to the deflecting component (column 3, lines 29-42).

Regarding claim 2, the guide device includes a handle (20) coupled to the guide tube, wherein the linkage system is carried within the handle (see Figure 2).

Regarding claim 4, Heinzelman et al disclose a method comprising providing a guide device as defined in claim 1, deploying the guide device into an interior tissue region, and operating the steering assembly to bend the distal end region of the guide tube (column 2, lines 35-40).

Claims 6-7 and 9 lack an inventive step under PCT Article 33(3) as being obvious over Heinzelman et al (US 5,364,351).

Regarding claim 6, Heinzelman et al disclose a guide device comprising a guide tube (14) defining a guide passage (see Figures 2 and 3) through which an operative tool (16) can be deployed into an interior body region, and a steering assembly (12) comprising a deflecting element (56) coupled to a distal end region of the guide tube to apply a deflecting force to bend the distal end region, an actuator (26), and a linkage system (18) coupling the actuator to the deflecting element to apply the deflecting force in response to operation of the actuator (column 3, lines 29-42), the linkage system including a slider (32) and a lever arm (34) coupled (via member 31) to the slider, the linkage system being operative to translate rotation of the actuator into linear movement of the slider and lever arm apply the deflecting force to the deflecting component (column 3, lines 29-42). Heinzelman does not disclose that the linkage system provides pivotal movement to the lever arm. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device disclosed by Heinzelman et al wherein the actuator causes pivotal movement of the lever arm or any other movement which would most efficiently and accurately provide deflection of the guide tube.

Regarding claim 7, the guide device includes a handle (20) coupled to the guide tube, wherein the linkage system is carried within the handle (see Figure 2).

Regarding claim 9, Heinzelman et al disclose a method comprising providing a guide device as defined in claim 1, deploying the guide device into an interior tissue region, and operating the steering assembly to bend the distal end region of the guide tube (column 2, lines 35-40).

Claims 3, 5, 8, and 10 lack an inventive step under PCT Article 33(3) as being obvious over Heinzelman et al (US 5,364,351) in view of Tanner et al (US 2003/0163085).

Regarding claims 3 and 8, Heinzelman et al substantially disclose the claimed invention as applied to claim 1. The disclosed device provides electrophysiologic therapy, but also disclose the assembly can be sued in many different environments (column 2, lines 30-35). Heinzelman et al do not disclose that the operative tool applies one or more fasteners to tissue. Tanner et al however teach a guide device for advancing and withdrawing an operative tool (200) wherein the operative tool applies one or more fasteners to the tissue (see paragraph [0062]) for the treatment of aortic aneurysms. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the guide device disclosed by Heinzelman et al wherein the tool provides a fastener to the tissue, as taught by Tanner et al, to provide a steering device that useful in the treatment of aortic aneurysms or other procedures where applying fasteners to a surgical site is desired.

Continued in Supplemental Box

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US06/33741

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:
Box V

Regarding claims 5 and 10, Heinzelman et al substantially disclose the claimed invention as applied to claim 1. Heinzelman et al discloses deploying the guide device into an interior tissue region, and operating the steering assembly to bend the distal end region of the guide tube (column 2, lines 35-42). The disclosed device provides electrophysiologic therapy, but also disclose the assembly can be sued in many different environments (column 2, lines 30-35). Heinzelman et al do not disclose passing the operative tool through the device to apply one or more fasteners to tissue. Tanner et al however teach a guide device for advancing and withdrawing an operative tool (200) wherein the operative tool applies one or more fasteners to the tissue (see paragraph [0062]) for the treatment of aortic aneurysms. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the guide device disclosed by Heinzelman et al wherein the tool passes through the guide device to provide a fastener to the tissue, as taught by Tanner et al, to provide a steering device that useful in the treatment of aortic aneurysms or other procedures where applying fasteners to a surgical site is desired.

Claims 1-10 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 18631-PCT	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/US06/33741	International filing date *(day/month/year)* 29 August 2006 (29.08.2006)	Priority date *(day/month/year)* 20 October 2005 (20.10.2005)
International Patent Classification (IPC) or national classification and IPC IPC: **A61F 11/00**(2006.01) USPC: 606/108		
Applicant APTUS ENDOSYSTEMS, INC.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☐ *(sent to the applicant and to the International Bureau)* a total of ___ sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) _____ , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand 17 May 2007 (17.05.2007)	Date of completion of this report 28 July 2007 (28.07.2007)
Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Authorized officer Allen Shoap *J. Hurley for* Telephone No. (571) 272-4391

Form PCT/IPEA/409 (cover sheet)(April 2005)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US06/33741

Box No. I Basis of the report

1. With regard to the **language**, this report is based on:

☒ the international application in the language in which it was filed.

☐ a translation of the international application into English, which is the language of a translation furnished for the purposes of:

- ☐ international search (under Rules 12.3 and 23.1(b))
- ☐ publication of the international application (under Rule 12.4(a))
- ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ the international application as originally filed/furnished

☒ the description:
pages 1-21 as originally filed/furnished
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____

☒ the claims:
pages 22-24 as originally filed/furnished
pages* NONE as amended (together with any statement) under Article 19
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____

☒ the drawings:
pages 1-9 as originally filed/furnished
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to the sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to the sequence listing (*specify*): _____

** If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US06/33741

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 3, 5-10	YES
	Claims 1-2, 4	NO
Inventive Step (IS)	Claims NONE	YES
	Claims 1-10	NO
Industrial Applicability (IA)	Claims 1-10	YES
	Claims NONE	NO

2. Citations and Explanations (Rule 70.7)
Please See Continuation Sheet

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**

Continuation of:

V. 2. Citations and Explanations:

Claims 1-2 and 4 lack novelty under PCT Article 33(2) as being anticipated by Heinzelman et al (US 5,364,351).

Regarding claim 1, Heinzelman et al disclose a guide device comprising a guide tube (14) defining a guide passage (see Figures 2 and 3) through which an operative tool (16) can be deployed into an interior body region, and a steering assembly (12) comprising a deflecting element (56) coupled to a distal end region of the guide tube to apply a deflecting force to bend the distal end region, an actuator (26), and a linkage system (18) coupling the actuator to the deflecting element to apply the deflecting force in response to operation of the actuator (column 3, lines 29-42), the linkage system including a rack (32) and a gear train (30) coupled to the rack, the linkage system being operative to translate rotation of the actuator into linear movement of the rack and rotation of the gear train to apply the deflecting force to the deflecting component (column 3, lines 29-42).

Regarding claim 2, the guide device includes a handle (20) coupled to the guide tube, wherein the linkage system is carried within the handle (see Figure 2).

Regarding claim 4, Heinzelman et al disclose a method comprising providing a guide device as defined in claim 1, deploying the guide device into an interior tissue region, and operating the steering assembly to bend the distal end region of the guide tube (column 2, lines 35-40).

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US06/33741

Supplemental Box

Claims 6-7 and 9 lack an inventive step under PCT Article 33(3) as being obvious over Heinzelman et al (US 5,364,351).

Regarding claim 6, Heinzelman et al disclose a guide device comprising a guide tube (14) defining a guide passage (see Figures 2 and 3) through which an operative tool (16) can be deployed into an interior body region, and a steering assembly (12) comprising a deflecting element (56) coupled to a distal end region of the guide tube to apply a deflecting force to bend the distal end region, an actuator (26), and a linkage system (18) coupling the actuator to the deflecting element to apply the deflecting force in response to operation of the actuator (column 3, lines 29-42), the linkage system including a slider (32) and a lever arm (34) coupled (via member 31) to the slider, the linkage system being operative to translate rotation of the actuator into linear movement of the slider and lever arm apply the deflecting force to the deflecting component (column 3, lines 29-42). Heinzelman does not disclose that the linkage system provides pivotal movement to the lever arm. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device disclosed by Heinzelman et al wherein the actuator causes pivotal movement of the lever arm or any other movement which would most efficiently and accurately provide deflection of the guide tube.

Regarding claim 7, the guide device includes a handle (20) coupled to the guide tube, wherein the linkage system is carried within the handle (see Figure 2).

Regarding claim 9, Heinzelman et al disclose a method comprising providing a guide device as defined in claim 1, deploying the guide device into an interior tissue region, and operating the steering assembly to bend the distal end region of the guide tube (column 2, lines 35-40).

Claims 3, 5, 8, and 10 lack an inventive step under PCT Article 33(3) as being obvious over Heinzelman et al (US 5,364,351) in view of Tanner et al (US 2003/0163085).

Regarding claims 3 and 8, Heinzelman et al substantially disclose the claimed invention as applied to claim 1. The disclosed device provides electrophysiologic therapy, but also disclose the assembly can be sued in many different environments (column 2, lines 30-35). Heinzelman et al do not disclose that the operative tool applies one or more fasteners to tissue. Tanner et al however teach a guide device for advancing and withdrawing an operative tool (200) wherein the operative tool applies one or more fasteners to the tissue (see paragraph [0062]) for the treatment of aortic aneurysms. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the guide device disclosed by Heinzelman et al wherein the tool provides a fastener to the tissue, as taught by Tanner et al, to provide a steering device that useful in the treatment of aortic aneurysms or other procedures where applying fasteners to a surgical site is desired.

Regarding claims 5 and 10, Heinzelman et al substantially disclose the claimed invention as applied to claim 1. Heinzelman et al discloses deploying the guide device into an interior tissue region, and operating the steering assembly to bend the distal end region of the guide tube (column 2, lines 35-42). The disclosed device provides electrophysiologic therapy, but also disclose the assembly can be sued in many different environments (column 2, lines 30-35). Heinzelman et al do not disclose passing the operative tool through the device to apply one or more fasteners to tissue. Tanner et al however teach a guide device for advancing and withdrawing an operative tool (200) wherein the operative tool applies one or more fasteners to the tissue (see paragraph [0062]) for the treatment of aortic aneurysms. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the guide device disclosed by Heinzelman et al wherein the tool passes through the guide device to provide a fastener to the tissue, as taught by Tanner et al, to provide a steering device that useful in the treatment of aortic aneurysms or other procedures where applying fasteners to a surgical site is desired.

Claims 1-10 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US06/33749

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61F 2/06 (2007.01)
USPC - 623/1.11
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61F 2/06 (2007.01)
USPC - 623/1.11

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
USPTO EAST System (US, USPG-PUB, EPO, DERWENT), MicroPatent.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2004/0138734 A1 to (CHOBOTOV et al) 15 July 2004 (15.07.2004) entire document	8-12, 19-21
--		----------
Y		1-7, 13-18
Y	US 2004/0093057 A1 (BOLDUC et al) 13 May 2004 (13.05.2004) entire document	1-7, 13-18

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
16 April 2007	15 AUG 2007
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
26 April 2007 (26.04.2007)

PCT

(10) International Publication Number
WO 2007/046955 A3

(51) International Patent Classification:
A61F 2/06 (2006.01)

(21) International Application Number:
PCT/US2006/033749

(22) International Filing Date: 29 August 2006 (29.08.2006)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
11/255,116 20 October 2005 (20.10.2005) US
11/254,619 20 October 2005 (20.10.2005) US

(71) Applicant *(for all designated States except US)*: **APTUS ENDOSYSTEMS, INC.** [US/US]; 777 North Pastoria Avenue, Sunnyvale, CA 94085 (US).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **BOLDUC, Lee** [US/US]; 716 Grape Avenue, Sunnyvale, CA 94087 (US). **LAROYA, Gilbert, S.** [US/US]; 4635 Armour Drive, Santa Clara, CA 95054 (US). **STAFFORD, Joshua** [US/US]; 1035 Windermere Avenue, Menlo Park, CA 94025 (US).

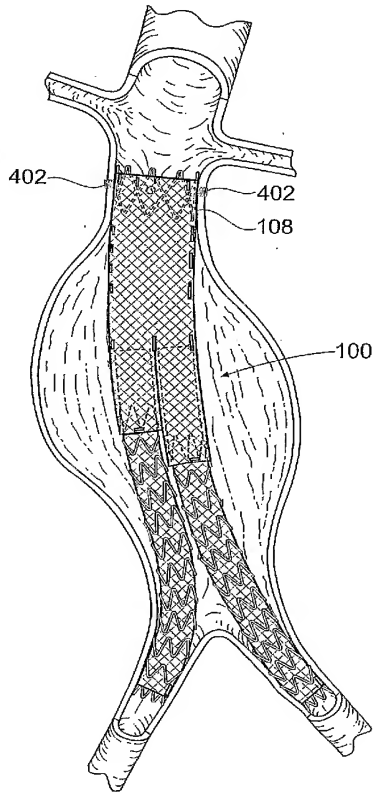
(74) Agents: **RYAN, Daniel, D.** et al.; Ryan, Kromholz, and Manion, S.C., P.O Box 26618, Brookfield, WI 53045 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT,

[Continued on next page]

(54) Title: DEVICES, SYSTEMS, AND METHODS FOR PROSTHESIS DELIVERY AND IMPLANTATION



(57) Abstract: Devices, systems, and methods use a catheter device sized and configured for introduction to a targeted site in a hollow body organ or blood vessel. The catheter device includes a first release mechanisms coupled to the prosthesis to secure at least one region of the prosthesis to the catheter shaft, and a second release mechanism coupled to the prosthesis in cooperation with the first release mechanism to prevent full release of the at least one region of the at least one region of the prosthesis from the catheter shaft after actuation of the first release mechanism. A fastening device sized and configured- for introduction to the targeted site in the hollow body organ or blood vessel occupied by the catheter device, includes an actuator to deploy a fastener in the at least one region of the prosthesis after actuation of the first release mechanism and before actuation of the second release mechanism.

WO 2007/046955 A3

RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

(88) Date of publication of the international search report:
25 October 2007

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: Daniel D. Ryan
P.O. BOX 26618
MILWAUKEE, WISCONSIN 53226-0618

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	15 AUG 2007
Applicant's or agent's file reference 19047-B PCT	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US06/33749	29 August 2006	20 October 2005

International Patent Classification (IPC) or both national classification and IPC
IPC(8) - A61F 2/06 (2007.01)
USPC - 623/1.11

Applicant APTUS ENDOSYSTEMS, INC.

1. This opinion contains indications relating to the following items:

- [X] Box No. I Basis of the opinion
- [ ] Box No. II Priority
- [ ] Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- [ ] Box No. IV Lack of unity of invention
- [X] Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- [ ] Box No. VI Certain documents cited
- [ ] Box No. VII Certain defects in the international application
- [ ] Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US	Date of completion of this opinion	Authorized officer:
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	16 April 2007	Blaine Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/237 (cover sheet) (April 2005)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US06/33749

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into _____ , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material

      ☐ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material

      ☐ on paper

      ☐ in electronic form

   c. time of filing/furnishing

      ☐ contained in the international application as filed

      ☐ filed together with the international application in electronic form

      ☐ furnished subsequently to this Authority for the purposes of search

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US06/33749

Box No. V **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1-7,13-17	YES
	Claims	8-12,18-21	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-21	NO
Industrial applicability (IA)	Claims	1-21	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1-7, 13-18 lack an inventive step under PCT Article 33(3) as being obvious over United States application number 2004/0138734 to Chobotov et al. hereafter referred to as Chobotov in view of United States application number 2004/0093057 to Bolduc et al. hereafter referred to as Buldoc.

Regarding claim 1, Chobotov discloses a system for delivering a prosthesis to a targeted site comprising a catheter device sized and configured for introduction to a targeted site in a hollow body organ or blood vessel, the catheter device including a shaft sized and configured to carry the prosthesis a during introduction of the catheter device (abstract; 425, figure 37A; 518, figure 37; paragraphs 202,208), a first release mechanism coupled to the prosthesis to secure at least one region of the prosthesis to the catheter shaft , and a first actuator to operate the first release mechanism, and a second release mechanism coupled to the prosthesis in cooperation with the first release mechanism to prevent full release of the at least one region of the at least one region of the prosthesis from the catheter shaft after actuation of the first actuator (paragraph 11), whereby actuation of the first actuator partially releases the at least one region of the prosthesis from the catheter shaft at the targeted site without fully releasing the at least one region from the catheter shaft (21,22,24 figures 6A,7A; paragraphs 76), and a second actuator to operate the second release mechanism to fully release the at least one region of the prosthesis from the catheter shaft (23,25 figures 6A,7A; paragraph 76). Chobotov does not disclose and a fastening device sized and configured for introduction to the targeted site in the hollow body organ or blood vessel occupied by the catheter device, the fastening device including an actuator to deploy a fastener in the at least one region of the prosthesis after actuation of the first release mechanism and before actuation of the second release mechanism. However, Bolduc discloses intraluminal prosthesis attachment system and method including actuator deploying fastener in a region of prosthesis after its placement (28,figures 20,21; paragraph 122). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Chobotov to include the fastening device taught by Bolduc for the purpose of making a prosthesis delivery system and method including fastening device having actuator fastening prosthesis to target anatomical region between actuation of release mechanisms.

Regarding claim 2, Chobotov and Bolduc disclose a system according to claim 1. Chobotov does not disclose wherein the second release mechanism comprises at least one stabilizing arm depending from the catheter shaft. However, Bolduc discloses intraluminal prosthesis attachment system and method including stabilization struts between the prosthesis and the catheter shaft (712,figure 41; paragraph 71). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Chobotov to include the struts taught by Bolduc for the purpose of making a prosthesis delivery system and method including stabilization arms depending from the catheter shaft.

Regarding claim 3, Chobotov and Bolduc disclose a system according to claim 1. Chobotov further discloses wherein the first release mechanism comprises a suture or filament or wire (24, figure 7B; paragraph 89).

Regarding claim 4, Chobotov and Bolduc disclose a system according to claim 1. Chobotov does not disclose further including a guide tube for guiding introduction of the fastening device. However, Bolduc discloses intraluminal prosthesis attachment system and method including delivery system for the fasteners (18, figure 15). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Chobotov to include the fastener delivery system taught by Bolduc for the purpose of making a prosthesis delivery system including a guide tube for the fastening device.

Regarding claim 5, Chobotov and Bolduc disclose a system according to claim 4. Chobotov does not disclose wherein the guide tube include a mechanism for remotely deflecting the guide tube. However, Bolduc discloses intraluminal prosthesis attachment system and method including a fastening device having controlling means (22, figure 15; paragraph 83). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Chobotov to include the control taught by Bolduc for the purpose of making a prosthesis delivery system and method including remote control mechanism for the fastening action.

Regarding claim 6, Chobotov and Bolduc disclose a system according to claim 1. Chobotov further discloses further including an interlock mechanism to prevent actuation of the second release mechanism without prior actuation of the first release mechanism (154, figure 71; paragraph 115).

Regarding claim 7 Chobotov and Bolduc disclose a system according to claim 1. Chobotov further discloses including a third release mechanism coupled to the prosthesis to release a second region of the prosthesis from the catheter shaft and a third actuator to operate the third release mechanism (48, figure 47; 475, figure 48; paragraphs 194, 195).

Continued in Supplemental Box

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:
Box V

Regarding claim 13, Chobotov discloses a system comprising a longitudinally compliant prosthesis having a proximal end and a distal end, a catheter device sized and configured for introduction to a targeted site in a hollow body organ or blood vessel (abstract; 10, figure 1;425, figure 37A; 518, figure 37; paragraphs 7,75,202,208), the first catheter device including a shaft sized and configured to carry the prosthesis during introduction of the catheter device (12, figure 1; paragraph 7,76), a first release mechanisms coupled to a proximal end of the prosthesis to secure the proximal end the prosthesis to the catheter shaft (23B,26 figure 7B; paragraph 94), and a first actuator to operate the first release mechanism (25, figure 6A; paragraph 76), a second release mechanism coupled to the proximal end of the prosthesis in cooperation with the first release mechanism to prevent full release of the proximal end of the prosthesis from the catheter shaft after actuation of the first actuator (154,150,154 figure 71), whereby actuation of the first actuator partially releases the proximal end prosthesis from the catheter shaft at the targeted site without fully releasing the proximal end of the prosthesis from the catheter shaft (paragraph 115), and a second actuator to operate the second release mechanism to fully release the proximal end of the prosthesis from the catheter shaft (158, figure 71), and a third release mechanism coupled to the distal end of the prosthesis independent of the first and second release mechanisms and a third actuator to operate the third release mechanism to fully release the distal end of the prosthesis from the catheter shaft (24,22B, figure 7B). Chobotov does not disclose and a fastening device sized and configured for introduction to the targeted site in the hollow body organ or blood vessel occupied by the catheter device, the fastening device including an actuator to deploy a fastener in the proximal end of the prosthesis after actuation of the first release mechanism and before actuation of the second and third release mechanisms. However, Bolduc discloses intraluminal prosthesis attachment system and method including actuator deploying fastener in a region of prosthesis after its placement (28,figures 20,21; paragraph 122). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Chobotov to include the fastening device taught by Bolduc for the purpose of making a prosthesis delivery system and method including fastening device having actuator fastening prosthesis to target anatomical region between actuation of release mechanisms.

Regarding claim 14, Chobotov and Bolduc disclose a system according to claim 13. Chobotov does not disclose wherein the second release mechanism comprises at least one stabilizing arm depending from the catheter shaft. However, Bolduc discloses intraluminal prosthesis attachment system and method including stabilization struts between the prosthesis and the catheter shaft (712,figure 41; paragraph 71). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Chobotov to include the struts taught by Bolduc for the purpose of making a prosthesis delivery system and method including stabilization arms depending from the catheter shaft.

Regarding claim 15, Chobotov and Bolduc disclose a system according to claim 13. Chobotov further discloses wherein the first release mechanism comprises a suture or filament or wire (24, figure 7B; paragraph 89).

Regarding claim 16, Chobotov and Bolduc disclose a system according to claim 13. Chobotov does not disclose further including a guide tube for guiding introduction of the fastening device. However, Bolduc discloses intraluminal prosthesis attachment system and method including delivery system for the fasteners (18, figure 15). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Chobotov to include the fastener delivery system taught by Bolduc for the purpose of making a prosthesis delivery system including a guide tube for the fastening device.

Regarding claim 17, Chobotov and Bolduc disclose a system according to claim 16. Chobotov does not disclose wherein the guide tube include a mechanism for remotely deflecting the guide tube. However, Bolduc discloses intraluminal prosthesis attachment system and method including a fastening device having controlling means (22, figure 15; paragraph 83). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Chobotov to include the control taught by Bolduc for the purpose of making a prosthesis delivery system and method including remote control mechanism for the fastening action.

Regarding claim 18, Chobotov and Bolduc disclose a system according to claim 13. Chobotov further discloses including an interlock mechanism to prevent actuation of the second release mechanism without prior actuation of the first release mechanism (154, figure 71; paragraph 115).

Claims 8-12, 19-21 lack novelty under PCT Article 33(2) as being anticipated by Chobotov.

Regarding claim 8, Chobotov discloses a method comprising positioning a deployment catheter at a targeted site in a hollow body organ or blood vessel, the deployment catheter carrying an expandable endovascular prosthesis (abstract; 425, figure 37A; 518, figure 37; paragraphs 202,208), actuating a first release mechanism on the deployment catheter to allow at least some expansion of at least one region of the prosthesis at the targeted site without fully releasing the one region of the prosthesis from the deployment catheter (28, figure 10), after actuating the first release mechanism (11,23,24, 84, figure 10; paragraphs 93), applying a fastener to fasten the at least one region of the prosthesis to the targeted site (30,32,33 figure 10), and after applying the fastener, actuating a second release mechanism on the deployment catheter to fully release the at least one region of the prosthesis from the deployment catheter (25,28,85 figure 11).

Regarding claim 9, Chobotov discloses a method according to claim 8. Chobotov further discloses comprising, after actuating the first release mechanism but before applying the fastener, adjusting a position of the deployment catheter either longitudinally and/or rotationally (paragraph 145).

Regarding claim 10, Chobotov discloses a method according to claim 8. Chobotov further discloses wherein applying a fastener includes deploying a second catheter that includes a fastener deployment mechanism (538, figure 37; 408, figure 26; paragraphs 188,205).

Regarding claim 11, Chobotov discloses a method according to claim 10. Chobotov further discloses wherein deploying the second catheter includes use of a guide tube through which the second catheter is introduced (800,430, 431,407,408, figure 61; paragraph 277).

Regarding claim 12, Chobotov discloses a method according to claim 8. Chobotov further discloses wherein the second release mechanism can be actuated only after actuation of the first release mechanism (155,158, figure 71; paragraph 115).

Continued in Next Supplemental Box

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US06/33749

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:
Previous Supplemental Box

Regarding claim 19, Chobotov discloses a method comprising positioning a deployment catheter at a targeted site in a hollow body organ or blood vessel (abstract), the deployment catheter carrying an expandable endovascular prosthesis (10, figure 1; paragraph 75), actuating a first release mechanism on the deployment catheter to allow at least some expansion of the proximal region of the prosthesis at the targeted site without fully releasing the proximal end of the prosthesis from the deployment catheter (443,figure 32; paragraph 181), after actuating the first release mechanism, applying a fastener to fasten the proximal end the prosthesis to the targeted site (466, figure 32; 407,figure 47; paragraph 122), after applying the fastener, actuating a second release mechanism on the deployment catheter to fully release the proximal end of the prosthesis from the deployment catheter (452, figure 32; paragraph 184), and after applying the fastener, actuating a third release mechanism on the deployment catheter to fully release the distal end of the prosthesis from the deployment catheter (476,481 figure 32; paragraph 193; 475, figure 475; paragraph 193).

Regarding claim 20, Chobotov discloses a method according to claim 19. Chobotov further discloses comprising, after actuating the first release mechanism, but before actuating either the second or third release mechanism, and also before applying the fastener, adjusting a position of the deployment catheter either longitudinally and/or rotationally (paragraph 145).

Regarding claim 21, Chobotov discloses a method according to claim 19. Chobotov further discloses wherein the second release mechanism can be actuated only after actuation of the first release mechanism (155,158, figure 71; paragraph 115).

Claims 1- 21 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 19047-B PCT	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/US06/33749	International filing date *(day/month/year)* 29 August 2006 (29.08.2006)	Priority date *(day/month/year)* 20 October 2005 (20.10.2005)
International Patent Classification (IPC) or national classification and IPC IPC: **A61F 2/06**(2006.01) USPC: 623/1.11		
Applicant APTUS ENDOSYSTEMS, INC.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☐ *(sent to the applicant and to the International Bureau)* a total of ___ sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) _____ , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:
   - ☒ Box No. I Basis of the report
   - ☐ Box No. II Priority
   - ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - ☐ Box No. IV Lack of unity of invention
   - ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - ☐ Box No. VI Certain documents cited
   - ☐ Box No. VII Certain defects in the international application
   - ☐ Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
17 May 2007 (17.05.2007)	05 June 2008 (05.06.2008) 18 JUN 2008
Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Authorized officer Tom Dunn Telephone No. 571 272-1700

Form PCT/IPEA/409 (cover sheet)(April 2007)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US06/33749

Box No. I Basis of the report

1. With regard to the **language**, this report is based on:

☒ the international application in the language in which it was filed.

☐ a translation of the international application into English, which is the language of a translation furnished for the purposes of:

- ☐ international search (under Rules 12.3(a) and 23.1(b))
- ☐ publication of the international application (under Rule 12.4(a))
- ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ the international application as originally filed/furnished

☒ the description:
pages 1-81 as originally filed/furnished
pages* NONE received by this Authority on
pages* NONE received by this Authority on

☒ the claims:
pages 82-86 as originally filed/furnished
pages* NONE as amended (together with any statement) under Article 19
pages* NONE received by this Authority on
pages* NONE received by this Authority on

☒ the drawings:
pages 1-44 as originally filed/furnished
pages* NONE received by this Authority on
pages* NONE received by this Authority on

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to the sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to the sequence listing (*specify*):

5. ☐ This report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 70.2(e)).

** If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US06/33749

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 1-7, 13-17	YES
	Claims 8-12, 18-21	NO
Inventive Step (IS)	Claims NONE	YES
	Claims 1-21	NO
Industrial Applicability (IA)	Claims 1-21	YES
	Claims NONE	NO

2. Citations and Explanations (Rule 70.7)
Please See Continuation Sheet

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US06/33749

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

V. 2. Citations and Explanations:

Claims 1-7, 13-18 lack an inventive step under PCT Article 33(3) as being obvious over United States application number 2004/0138734 to Chobotov et al. hereafter referred to as Chobotov in view of United States application number 2004/0093057 to Bolduc et al. hereafter referred to as Buldoc.

Regarding claim 1, Chobotov discloses a system for delivering a prosthesis to a targeted site comprising a catheter device sized and configured for introduction to a targeted site in a hollow body organ or blood vessel, the catheter device including a shaft sized and configured to carry the prosthesis a during introduction of the catheter device (abstract; 425, figure 37A; 518, figure 37; paragraphs 202,208), a first release mechanism coupled to the prosthesis to secure at least one region of the prosthesis to the catheter shaft , and a first actuator to operate the first release mechanism, and a second release mechanism coupled to the prosthesis in cooperation with the first release mechanism to prevent full release of the at least one region of the at least one region of the prosthesis from the catheter shaft after actuation of the first actuator (paragraph 11), whereby actuation of the first actuator partially releases the at least one region of the prosthesis from the catheter shaft at the targeted site without fully releasing the at least one region from the catheter shaft (21,22,24 figures 6A,7A; paragraphs 76), and a second actuator to operate the second release mechanism to fully release the at least one region of the prosthesis from the catheter shaft (23,25 figures 6A,7A; paragraph 76). Chobotov does not disclose and a fastening device sized and configured for introduction to the targeted site in the hollow body organ or blood vessel occupied by the catheter device, the fastening device including an actuator to deploy a fastener in the at least one region of the prosthesis after actuation of the first release mechanism and before actuation of the second release mechanism. However, Bolduc discloses intraluminal prosthesis attachment system and method including actuator deploying fastener in a region of prosthesis after its placement (28,figures 20,21; paragraph 122). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Chobotov to include the fastening device taught by Bolduc for the purpose of making a prosthesis delivery system and method including fastening device having actuator fastening prosthesis to target anatomical region between actuation of release mechanisms.

Regarding claim 2, Chobotov and Bolduc disclose a system according to claim 1. Chobotov does not disclose wherein the second release mechanism comprises at least one stabilizing arm depending from the catheter shaft. However, Bolduc discloses intraluminal

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US06/33749

Supplemental Box

prosthesis attachment system and method including stabilization struts between the prosthesis and the catheter shaft (712,figure 41; paragraph 71). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Chobotov to include the struts taught by Bolduc for the purpose of making a prosthesis delivery system and method including stabilization arms depending from the catheter shaft.

Regarding claim 3, Chobotov and Bolduc disclose a system according to claim 1. Chobotov further discloses wherein the first release mechanism comprises a suture or filament or wire (24, figure 7B; paragraph 89).

Regarding claim 4, Chobotov and Bolduc disclose a system according to claim 1. Chobotov does not disclose further including a guide tube for guiding introduction of the fastening device. However, Bolduc discloses intraluminal prosthesis attachment system and method including delivery system for the fasteners (18, figure 15). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Chobotov to include the fastener delivery system taught by Bolduc for the purpose of making a prosthesis delivery system including a guide tube for the fastening device.

Regarding claim 5, Chobotov and Bolduc disclose a system according to claim 4. Chobotov does not disclose wherein the guide tube include a mechanism for remotely deflecting the guide tube. However, Bolduc discloses intraluminal prosthesis attachment system and method including a fastening device having controlling means (22, figure 15; paragraph 83). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Chobotov to include the control taught by Bolduc for the purpose of making a prosthesis delivery system and method including remote control mechanism for the fastening action.

Regarding claim 6, Chobotov and Bolduc disclose a system according to claim 1. Chobotov further discloses further including an interlock mechanism to prevent actuation of the second release mechanism without prior actuation of the first release mechanism (154, figure 71; paragraph 115).

Regarding claim 7 Chobotov and Bolduc disclose a system according to claim 1. Chobotov further discloses including a third release mechanism coupled to the prosthesis to release a second region of the prosthesis from the catheter shaft and a third actuator to operate the third release mechanism (48, figure 47; 475, figure 48; paragraphs 194, 195).

Regarding claim 13, Chobotov discloses a system comprising a longitudinally compliant prosthesis having a proximal end and a distal end, a catheter device sized and configured for introduction to a targeted site in a hollow body organ or blood vessel (abstract; 10, figure 1;425, figure 37A; 518, figure 37; paragraphs 7,75,202,208), the first catheter device including a shaft sized and configured to carry the prosthesis during introduction of the catheter device (12, figure 1; paragraph 7,76), a first release mechanisms coupled to a proximal end of the prosthesis to secure the proximal end the prosthesis to the catheter shaft (23B,26 figure 7B; paragraph 94), and a first actuator to operate the first release mechanism (25, figure 6A; paragraph 76), a second release mechanism coupled to the proximal end of the prosthesis in cooperation with the first release mechanism to prevent full release of the proximal end of the prosthesis from the catheter shaft after actuation of the first actuator (154,150,154 figure 71), whereby actuation of the first actuator partially releases the proximal end prosthesis from the catheter shaft at the targeted site without fully releasing the proximal end of the prosthesis from the catheter shaft (paragraph 115), and a second actuator to operate the second release mechanism to fully release the proximal end of the prosthesis from the catheter shaft (158, figure 71), and a third release mechanism coupled to the distal end of the prosthesis independent of the first and second release mechanisms and a third actuator to operate the third release mechanism to fully release the distal end of the prosthesis from the catheter shaft (24,22B, figure 7B). Chobotov does not disclose and a fastening device sized and configured for introduction to the targeted site in the hollow body organ or blood vessel occupied by the catheter device, the fastening device including an actuator to deploy a fastener in the proximal end of the prosthesis after actuation of the first release mechanism and before actuation of the second and third release mechanisms. However, Bolduc discloses intraluminal prosthesis attachment system and method including actuator deploying fastener in a region of prosthesis after its placement (28,figures 20,21; paragraph 122). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Chobotov to include the fastening device taught by Bolduc for the purpose of making a prosthesis delivery system and method including fastening device having actuator fastening prosthesis to target anatomical region between actuation of release mechanisms.

Regarding claim 14, Chobotov and Bolduc disclose a system according to claim 13. Chobotov does not disclose wherein the second release mechanism comprises at least one stabilizing arm depending from the catheter shaft. However, Bolduc discloses intraluminal prosthesis attachment system and method including stabilization struts between the prosthesis and the catheter shaft (712,figure 41; paragraph 71). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Chobotov to include the struts taught by Bolduc for the purpose of making a prosthesis delivery system and method including stabilization arms depending from the catheter shaft.

Regarding claim 15, Chobotov and Bolduc disclose a system according to claim 13. Chobotov further discloses wherein the first release mechanism comprises a suture or filament or wire (24, figure 7B; paragraph 89).

Regarding claim 16, Chobotov and Bolduc disclose a system according to claim 13. Chobotov does not disclose further including a guide tube for guiding introduction of the fastening device. However, Bolduc discloses intraluminal prosthesis attachment system and method including delivery system for the fasteners (18, figure 15). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Chobotov to include the fastener delivery system taught by Bolduc for the purpose of making a prosthesis delivery system including a guide tube for the fastening device.

Regarding claim 17, Chobotov and Bolduc disclose a system according to claim 16. Chobotov does not disclose wherein the guide tube include a mechanism for remotely deflecting the guide tube. However, Bolduc discloses intraluminal prosthesis attachment system and method including a fastening device having controlling means (22, figure 15; paragraph 83). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Chobotov to include the control taught by Bolduc for the purpose of making a prosthesis delivery system and method including remote control mechanism for the fastening action.

Regarding claim 18, Chobotov and Bolduc disclose a system according to claim 13. Chobotov further discloses including an interlock mechanism to prevent actuation of the second release mechanism without prior actuation of the first release mechanism (154, figure 71;

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US06/33749

Supplemental Box

paragraph 115).

Claims 8-12, 19-21 lack novelty under PCT Article 33(2) as being anticipated by Chobotov.

Regarding claim 8, Chobotov discloses a method comprising positioning a deployment catheter at a targeted site in a hollow body organ or blood vessel, the deployment catheter carrying an expandable endovascular prosthesis (abstract; 425, figure 37A; 518, figure 37; paragraphs 202,208), actuating a first release mechanism on the deployment catheter to allow at least some expansion of at least one region of the prosthesis at the targeted site without fully releasing the one region of the prosthesis from the deployment catheter (28, figure 10), after actuating the first release mechanism (11,23,24, 84, figure 10; paragraphs 93), applying a fastener to fasten the at least one region of the prosthesis to the targeted site (30,32,33 figure 10), and after applying the fastener, actuating a second release mechanism on the deployment catheter to fully release the at least one region of the prosthesis from the deployment catheter (25,28,85 figure 11).

Regarding claim 9, Chobotov discloses a method according to claim 8. Chobotov further discloses comprising, after actuating the first release mechanism but before applying the fastener, adjusting a position of the deployment catheter either longitudinally and/or rotationally (paragraph 145).

Regarding claim 10, Chobotov discloses a method according to claim 8. Chobotov further discloses wherein applying a fastener includes deploying a second catheter that includes a fastener deployment mechanism (538, figure 37; 408, figure 26; paragraphs 188,205).

Regarding claim 11, Chobotov discloses a method according to claim 10. Chobotov further discloses wherein deploying the second catheter includes use of a guide tube through which the second catheter is introduced (800,430, 431,407,408, figure 61; paragraph 277).

Regarding claim 12, Chobotov discloses a method according to claim 8. Chobotov further discloses wherein the second release mechanism can be actuated only after actuation of the first release mechanism (155,158, figure 71; paragraph 115).

Regarding claim 19, Chobotov discloses a method comprising positioning a deployment catheter at a targeted site in a hollow body organ or blood vessel (abstract), the deployment catheter carrying an expandable endovascular prosthesis (10, figure 1; paragraph 75), actuating a first release mechanism on the deployment catheter to allow at least some expansion of the proximal region of the prosthesis at the targeted site without fully releasing the proximal end of the prosthesis from the deployment catheter (443,figure 32; paragraph 181), after actuating the first release mechanism, applying a fastener to fasten the proximal end the prosthesis to the targeted site (466, figure 32; 407,figure 47; paragraph 122), after applying the fastener, actuating a second release mechanism on the deployment catheter to fully release the proximal end of the prosthesis from the deployment catheter (452, figure 32; paragraph 184), and after applying the fastener, actuating a third release mechanism on the deployment catheter to fully release the distal end of the prosthesis from the deployment catheter (476,481 figure 32; paragraph 193; 475, figure 475; paragraph 193).

Regarding claim 20, Chobotov discloses a method according to claim 19. Chobotov further discloses comprising, after actuating the first release mechanism, but before actuating either the second or third release mechanism, and also before applying the fastener, adjusting a position of the deployment catheter either longitudinally and/or rotationally (paragraph 145).

Regarding claim 21, Chobotov discloses a method according to claim 19. Chobotov further discloses wherein the second release mechanism can be actuated only after actuation of the first release mechanism (155,158, figure 71; paragraph 115).

Claims 1- 21 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

---------- NEW CITATIONS ----------

NONE

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
26 April 2007 (26.04.2007)

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(10) International Publication Number
WO 2007/046954 A3

(51) International Patent Classification:
A61B 17/10 (2006.01) *A61B 17/04* (2006.01)
A61B 17/08 (2006.01)

(21) International Application Number:
PCT/US2006/033747

(22) International Filing Date: 29 August 2006 (29.08.2006)

(25) Filing Language: English

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(30) Priority Data:
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11/254,619 20 October 2005 (20.10.2005) US

(71) Applicant *(for all designated States except US)*: **APTUS ENDOSYSTEMS, INC.** [US/US]; 777 North Pastoria Avenue, Sunnyvale, CA 94085 (US).

(72) Inventor; and
(75) Inventor/Applicant *(for US only)*: **BOLDUC, Lee** [US/US]; 716 Grape Avenue, Sunnyvale, CA 94087 (US).

(74) Agent: **RYAN, Daniel, D.**; Ryan, Kromholz & Manion, S.C., P.O. Box 26618, Brookfield WI 53045 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

(88) Date of publication of the international search report:
20 November 2008

(54) Title: DEVICES, SYSTEMS, AND METHODS FOR PROSTHESIS DELIVERY AND IMPLANTATION, INCLUDING THE USE OF A FASTENER TOOL

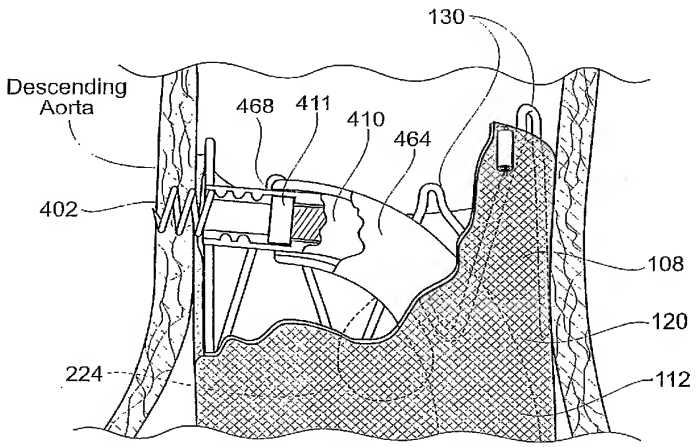

Fig. 66

(57) Abstract: Devices, systems, and methods for implanting radially expandable prostheses in the body lumens rely on tacking or anchoring the prostheses with separately introduced fasteners. The prostheses may be self- expanding or balloon expandable, and may include a single lumen or more than one lumen. After initial placement, a fastener applier system is introduced within the expanded prostheses to deploy a plurality of fasteners to at least one prosthesis end. The fasteners are usually helical fasteners which are releasably restrained on the fastener driver, and are delivered by rotation of the fastener driver. The fasteners may be applied singly, typically in circumf erentially spaced- apart patterns about the interior of at least one end of the prosthesis. A lumen extension or lumens may be coupled to the prosthesis to extend the reach of the prosthesis within the implantation site. Fasteners may also be applied to the lumen extensions .

WO 2007/046954 A3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US06/33747

A. CLASSIFICATION OF SUBJECT MATTER
IPC: **A61B 17/10**(2006.01);**A61B 17/08**(2006.01);**A61B 17/04**(2006.01)

USPC: 606/143,213;227/175.1
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 606/139-143, 151, 213; 227/175.1-182.1, 901

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 2004/0093057 A1 (BOLDUC et al.) 13 May 2004 (13.05.2004), paragraph [0088]-[0116], figures 7-25	1-3, 5-22 --- 4
Y	US 2005/0187613 A1 (BOLDUC et al.) 25 August 205 (25.08.2005), paragraph [0129]	4

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search
13 June 2008 (13.06.2008)

Date of mailing of the international search report
08 JUL 2008

Name and mailing address of the ISA/US
Mail Stop PCT, Attn: ISA/US
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Authorized officer
Jackie Ho
Telephone No. (571) 272-3700

Form PCT/ISA/210 (second sheet) (April 2007)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
KROMHOLZ RYAN
P.O. BOX 26618
BROOKFIELD, WI 53045

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing (*day/month/year*)	08 JUL 2008
Applicant's or agent's file reference 19047-C PCT	FOR FURTHER ACTION See paragraph 2 below

International application No.	International filing date (*day/month/year*)	Priority date (*day/month/year*)
PCT/US06/33747	29 August 2006 (29.08.2006)	20 October 2005 (20.10.2005)

International Patent Classification (IPC) or both national classification and IPC

IPC: **A61B 17/10**(2006.01);**A61B 17/08**(2006.01);**A61B 17/04**(2006.01)
USPC: 606/143,213;227/175.1

Applicant

APTUS ENDOSYSTEMS, INC

1. This opinion contains indications relating to the following items:

- ☒ Box No. I — Basis of the opinion
- ☐ Box No. II — Priority
- ☐ Box No. III — Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV — Lack of unity of invention
- ☒ Box No. V — Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI — Certain documents cited
- ☐ Box No. VII — Certain defects in the international application
- ☐ Box No. VIII — Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(*b*) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US	Date of completion of this opinion	Authorized officer
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	16 June 2008 (16.06.2008)	Jackie Ho Telephone No. (571) 272-3700

Form PCT/ISA/237 (cover sheet) (April 2007)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US06/33747

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of:

   a. type of material

      ☐ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material

      ☐ on paper

      ☐ in electronic form

   c. time of filing/furnishing

      ☐ contained in the international application as filed.

      ☐ filed together with the international application in electronic form.

      ☐ furnished subsequently to this Authority for the purposes of search.

4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US06/33747

Box No. V Reasoned statement under Rule 43 *bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 4	YES
	Claims 1-3 and 5-22	NO
Inventive step (IS)	Claims NONE	YES
	Claims 1-22	NO
Industrial applicability (IA)	Claims 1-22	YES
	Claims NONE	NO

2. Citations and explanations:

Claims 1-3 and 5-22 lack novelty under PCT Article 33(2) as being anticipated by Bolduc et al. (2004/0093057).

Bolduc (2004/0093057) discloses a fastener applier (27) for securing a prosthesis comprising a handle assembly (108) positioned at the caudal end of the fastener applier (Fig. 14), a fastener applier shaft (30) coupled to the handle assembly (Fig. 14), and a fastener driver (100) for advancing a fastener into the prosthesis and tissue (Fig. 15-19), the fastener driver coupled to the fastener applier shaft at the cephalad end of the fastener applier shaft (Fig. 14A), the fastener driver including a housing (outer tube in Fig. 14A) and a release latch(102), wherein the release latch prevents premature release of the fastener from the fastener driver; and a method of installing a fastener to a fastener applier by placing the fastener (28) to the driver (100) of the fastener applier (27) ([0089]-[0091]).
Bolduc (2004/0093057) also discloses that the fastener driver housing includes an internally threaded portion (32) (Fig. 14A) and a non-threaded portion (proximal end of the housing) ([0091]); that the handle assembly further includes a motion control assembly to be used by an operator, the motion control assembly providing motion control of the fastener within the fastener driver ([0105]); that the handle assembly further includes an indication assembly to provide information to an operator, the indication assembly providing at least one of an audible and visual indication ([0116]); that the information includes at least one of a fastener position or timing or status or error, or any combination ([0115-0116); that the fastener (28) is a helical fastener (Fig. 18); that the helical fastener includes a fastener body having a distal end for penetrating tissue in response to a force and a proximal end for releasably coupling the fastener body to the fastener applier (Fig. 18), and a stop structure (146) associated with the proximal end to prevent over-penetration of the fastener body into tissue, the stop structure bisecting the diameter of the fastener body (Fig. 18); and that the stop structure is offset from the diameter of the fastener body (Fig. 18).
Furthermore, Bolduc (2004/0093057) discloses an apparatus (27) for storing a fastener for securing a prosthesis (28) comprising a base structure (the housing seen in Fig. 14A), and at least one receptacle (100) positioned within the base structure, the receptacle sized and configured to releasably store at least one fastener (28) (Fig. 14A); and including a post (102) positioned within the receptacle to releasably restrain the fastener; that the fastener is releasably restrained within the receptacle by friction between the fastener and the receptacle wall (Fig. 14A).

Claim 4 lack an inventive step under PCT Article 33(3) as being obvious over Bolduc et al. (2004/0093057) in view of Bolduc et al. (2005/0187613).

Bolduc (2004/0093057) teaches all the limitations discussed above, however Bolduc (2004/0093057) does not disclose that the motion control assembly includes a forward control function and a reverse control function.
Bolduc et al. (2005/0187613) discloses a fastener applier with a forward control function and a reverse control function ([0129]).
It would have been obvious for a person of ordinary skill in the art to add a forward and reverse function to the motion control since it is well known in the art that motors can move in both the forward and reverse direction which would allow for removing the device if placed incorrectly.

Claims 1-22 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
9 September 2005 (09.09.2005)

PCT

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A61B 17/10 (2006.01) *A61F 2/06* (2006.01)

(21) International Application Number:
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(22) International Filing Date:
22 February 2005 (22.02.2005)

(25) Filing Language: English

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(30) Priority Data:
10/786,465 25 February 2004 (25.02.2004) US

(71) Applicant *(for all designated States except US)*: **APTUS ENDOSYSTEMS, INC.** [US/US]; 777 North Pastoria Avenue, Sunnyvale, CA 94085 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **BOLDUC, Lee** [US/US]; 716 Grape Avenue, Sunnyvale, CA 94087 (US). **HOULE, Philip, R.** [US/US]; 1586 Benton Street, Sunnyvale, CA 94087 (US).

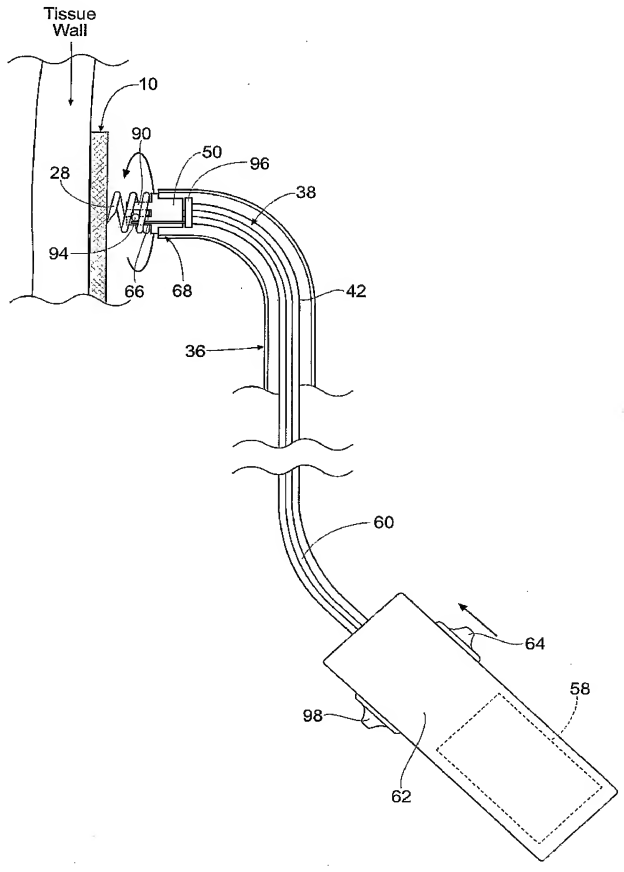
(74) Agents: **RYAN, Daniel, D.** et al.; P.O. Box 26618, Milwaukee, WI 53226 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

[Continued on next page]

(54) Title: SYSTEM AND METHOD FOR ATTACHING AN INTERNAL PROSTHESIS



(57) Abstract: Systems and methods introduce and deploy prosthesis into a blood vessel or hollow body organ by intra-vascular access. The prosthesis (20) is secured in place by fasteners (28), which are implanted by an applier (62) that is also deployed by intra-vascular access. The applier is configured to permit controlled, selective release of the fastener in a step that is independent of the step of implantation.

WO 2005/081936 A3

Published:

— *with international search report*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

(88) Date of publication of the international search report:
8 November 2007

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US05/05627

A. CLASSIFICATION OF SUBJECT MATTER
IPC: **A61B 17/10**(2006.01);**A61F 2/06**(2006.01)

USPC: 606/138,139,140,142,143;623/1.23
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 606/138,139,140,142,143;623/1.23

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,334,196 A (SCOTT et al) 2 August 1994 (02.08.1994), abstract, col. 4, ll. 62,col. 6, ll. 37,38	1-7,17-47

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
05 August 2007 (05.08.2007)	25 SEP 2007
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Authorized officer Jackie Ho Telephone No. (571)-272-9969

Form PCT/ISA/210 (second sheet) (April 2005)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
DANIEL D. RYAN
P.O. BOX 26618
MILWAUKEE, WI 53226-0618

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Applicant's or agent's file reference 18514-PCT	Date of mailing (*day/month/year*) 25 SEP 2007 **FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date (*day/month/year*)	Priority date (*day/month/year*)
PCT/US05/05627	22 February 2005 (22.02.2005)	25 February 2004 (25.02.2004)

International Patent Classification (IPC) or both national classification and IPC

IPC: **A61B 17/10**(2006.01);**A61F 2/06**(2006.01)
USPC: 606/138,139,140,142,143;623/1.23

Applicant

APTUS ENDOSYSTEMS, INC

1. This opinion contains indications relating to the following items:

- ☒ Box No. I — Basis of the opinion
- ☐ Box No. II — Priority
- ☐ Box No. III — Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV — Lack of unity of invention
- ☒ Box No. V — Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI — Certain documents cited
- ☐ Box No. VII — Certain defects in the international application
- ☐ Box No. VIII — Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(*b*) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US	Date of completion of this opinion	Authorized officer
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	05 August 2007 (05.08.2007)	Jackie Ho Telephone No. (571)-272-9969

Form PCT/ISA/237 (cover sheet) (April 2005)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US05/05627

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

☒ the international application in the language in which it was filed

☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ on paper

☐ in electronic form

c. time of filing/furnishing

☐ contained in the international application as filed.

☐ filed together with the international application in electronic form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US05/05627

Box No. V Reasoned statement under Rule 43 *bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 8-16	YES
	Claims 1-7,17-47	NO
Inventive step (IS)	Claims 8-16	YES
	Claims 1-7 and 17-47	NO
Industrial applicability (IA)	Claims 1-47	YES
	Claims NONE	NO

2. Citations and explanations:

Claims 1-7 and 17-47 lack novelty under PCT Article 33(2) as being anticipated by Scott et al. (U.S. Patent No. 5,334,196).

Claims 1-4,8,17-22,24-26,28-32:Scott teaches a tool for applying an implantation force to a fastener sized and configured for implantation in tissue in response to an implantation force applied according to prescribed conditions, the tool comprising a tool body (12), a driven member carried by the tool body and being operable to apply the implantation force (35, Fig. 4), a mechanism on the driven member to couple the fastener to the driven member to transfer the implantation force from the driven member to the fastener (28, Fig. 2), a controller coupled to the driven member (36), the controller including an initial phase operating the driven member to apply the implantation force under conditions than are short of the prescribed conditions (with 36 is moved it applies the implantation force), a lull phase commencing at the end of the initial phase interrupting operation of the driven member (the lull phase is inherently the time period after the implantation), a final phase operating the driven member under conditions that supplement the conditions of the initial phase to achieve the prescribed conditions (Fig. 5), the controller requiring, after the initial phase, a prescribed command to advance from the lull phase to the final phase (the prescribed command is the trigger being activated, 36, Fig. 4).
Claims 33 and 34:Scott teaches the prescribed command is based on input from an operator and upon input reflecting a sensed operating condition (inherently using 36 is input from an operator, the sensed operating condition is when the latch of 48 moves, col. 6, ll. 37,38).
Claims 5,35:Scott teaches the driven member is also operable to apply a removal force to withdraw the fastener from tissue (Fig. 6, 24 applies force), and wherein the controller includes a removal phase operating the driven member to apply the removal force (Fig. 6), the controller requiring, after the initial phase, a different prescribed command to advance from the lull phase to the removal phase (moving 36, col. 4, ll. 62).
Claims 6,23,27,36:Scott teaches the driven member is rotated in one direction to apply the implantation force (32 pivots, col. 4, ll. 62) and rotated in an opposite direction to apply the removal force (Figs. 4 and 6).
Claims 7,38 and 39:Scott teaches the tool body includes a tube (8) that carries the driven member (32/36) and the driven member is rotated (rotates, 124, Fig. 5) to apply the implantation force.
Claims 40-47:Scott teaches coupling a fastener to the driven member, accessing a tissue region, operating the driven member during the initial phase to partially implant the fastener in the tissue region (abstract line 2 and 3), deciding during the lull phase to commence the final phase, entering the prescribed command to advance from the lull phase to the final phase (col. 4, ll. 62), thereby completing the implantation of the fastener in the tissue region.

Claims 8-16 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest Scott does not have a receptacle and all the limitations taught in claim 1 of the current application.

Claims 1-47 meet the criteria set out in PCT Article 33(4), and thus is useful to the art in industrial applicability because the subject matter claimed can be made or used in industry.

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:
DANIEL D. RYAN
P.O. BOX 26618
MILWAUKEE, WI 53226-0618

PCT

NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of Mailing (*day/month/year*)	
Applicant's or agent's file reference 18514-PCT	**IMPORTANT NOTIFICATION**

International application No.	International filing date (*day/month/year*)	Priority date (*day/month/year*)
PCT/US05/05627	22 February 2005 (22.02.2005)	25 February 2004 (25.02.2004)

Applicant

APTUS ENDOSYSTEMS, INC

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/US	Authorized officer
Mail Stop PCT, Attn: IPEA/ US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450	Jackie Ho
Facsimile No. (571) 273-3201	Telephone No. (571)-272-9969

Form PCT/IPEA/416 (July 1992)

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:
DANIEL D. RYAN
P.O. BOX 26618
MILWAUKEE, WI 53226-0618

PCT

NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of Mailing *(day/month/year)*	07 APR 2009
Applicant's or agent's file reference 18514-PCT	**IMPORTANT NOTIFICATION**

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US05/05627	22 February 2005 (22.02.2005)	25 February 2004 (25.02.2004)

Applicant

APTUS ENDOSYSTEMS, INC

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/ US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Authorized officer Jackie Ho Telephone No. (571)-272-9969

Form PCT/IPEA/416 (July 1992)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 18514-PCT	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/US05/05627	International filing date *(day/month/year)* 22 February 2005 (22.02.2005)	Priority date *(day/month/year)* 25 February 2004 (25.02.2004)
International Patent Classification (IPC) or national classification and IPC IPC: **A61B 17/10**(2006.01);**A61F 2/06**(2006.01) USPC: 606/138,139,140,142,143:623/1.23		
Applicant APTUS ENDOSYSTEMS, INC		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of ___ sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of report with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
25 September 2007 (25.09.2007)	13 March 2009 (13.03.2009)
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/ US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Authorized officer Jackie Ho Telephone No. (571)-272-9969

Form PCT/IPEA/409 (cover sheet)(July 1998)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US05/05627

I. Basis of the report

1. With regard to the **elements** of the international application:*

☒ the international application as originally filed.

☒ the description:
pages 1-47 as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____.

☒ the claims:
pages 1-9 , as originally filed
pages NONE , as amended (together with any statement) under Article 19
pages NONE , filed with the demand
pages NONE , filed with the letter of _____.

☒ the drawings:
pages 1-25 , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____.

☐ the sequence listing part of the description:
pages NONE , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____.

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination(under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in printed form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:

☒ the description, pages none

☒ the claims, Nos. none

☒ the drawings, sheets/~~fig~~ none

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

** Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*
*** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US05/05627

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims 8-16	YES
	Claims 1-7,17-47	NO
Inventive Step (IS)	Claims 8-16	YES
	Claims 1-7,17-47	NO
Industrial Applicability (IA)	Claims 1-47	YES
	Claims NONE	NO

2. CITATIONS AND EXPLANATIONS

Claims 1-7 and 17-47 lack novelty under PCT Article 33(2) as being anticipated by Scott et al. (U.S. Patent No. 5,334,196).

Claims 1-4,8,17-22,24-26,28-32:Scott teaches a tool for applying an implantation force to a fastener sized and configured for implantation in tissue in response to an implantation force applied according to prescribed condition, the tool comprising a tool body (12), a driven member carried by the tool body and being operable to apply the implantation force (35, Fig. 4), a mechanism on the driven member to couple the fastener to the driven member to transfer the implantation force from the driven member to the fastener (28, Fig. 2), a controller coupled to the driven member (36), the controller including an initial phase operating the driven member to apply the implantation force under conditions than are short of the prescribed condition (with 36 is moved it applies the implantation force), a hall phase commencing at the end of the initial phase interrupting operation of the driven member (the lull phase is inherently the time period after the implantation), a final phase operating the driven member under conditions that supplement the conditions of the initial phase to achieve the prescribed conditions (Fig. 5), the controller requiring, after the initial phase, a prescribed command to advance from the lull phase to the phase (the prescribed command is the trigger being activated, 36, Fig. 4).

Claims 33 and 34:Scott teaches the prescribed command is based on input from an operator and upon input reflecting a sensed operating condition (inherently using 36 is input from an operator, the sensed operating condition is when the latch of 48 moves, col. 6, 11. 37,38).

Claims 5,35:Scott teaches the driven member is also operable to apply a removal force to withdraw the fastener from tissue (Fig. 6, 24 applies force), and wherein the controller includes a removal phase operating the driven member to apply the removal force (Fig. 6), the controller requiting, after the initial phase, a different prescribed command to advance from the lull phase to the removal phase (moving 36, col. 4, 11. 62).

Claims 6,23,27,36:Scott teaches the driven member is rotated in one direction to apply the implantation force (32 pivots, col. 4, 11.62) and rotated in an opposite direction to apply the removal force (Figs. 4 and 6).

Claims 7,38 and 39:Scott teaches the tool body includes a tube (8) that carries the driven member (32/36) and the driven member is rotated (rotates, 124, Fig. 5) to apply the implantation force.

Claims 40-47 :Scott teaches coupling a fastener to the driven member, accessing a tissue region, operating the driven member during the initial phase to partially implant the fastener in the tissue region (abstract line 2 and 3), deciding during the lull phase to commence the ftml phase, entering the prescribed command to advance from the lull phase to the final phase (col. 4, 11. 62), thereby completing the implamation of the fastener in the tissue region.

Claims 8-16 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest Scott does not have a receptacle and all the limitations taught in claim 1 of the current application. Claims 1-47 meet the criteria set out in PCT Article 33(4), and thus is useful to the art in industrial applicability because the subject matter claimed can be made or used in industry.

---------- NEW CITATIONS ----------

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 06/37085

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) -- A61F 2/06 (2007.01)
USPC -- 623/1.36, 623/1.11
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
USPC -- 623/1.36, 623/1.11

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WEST -- PGPB,USPT,USOC,EPAB,JPAB; Dialog Classic files 2, 351; Google Patents; USPTO Web Page
Search terms -- catheter guide, fastener applier, instructions, marker indicia, sensor, current, filament, implantation, lumen, controller, actuator, driver, seal, aneurysm

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2003/0100943 A1 (BOLDUC) 29 May 2003 (29.05.2003); para [0005], [0008], [0009], [0012]-[0014], [0037]	1-29
Y	US 6,273,858 B1 (FOX et al.) 14 August 2001 (14.08.2001); col 6, ln 15-31	1-11
Y	US 2002/0156365 A1 (TSEKOS) 24 October 2002 (24.10.2002); para [0024], [050], [0052], [0069]-[0071], [0075]	9-19
Y	US 2004/0054352 A1 (ADAMS et al.) 18 March 2004 (18.03.2004); para [0032], [0033], [0048]	12-29
Y	US 2004/0002731 A1 (AGANON et al.) 01 January 2004 (01.01.2004); para [0007], [0075]	12-29

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
23 May 2007 (23.05.2007)	30 AUG 2007
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (April 2005)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: Daniel D. Ryan
P.O. Box 26618
Milwaukee, Wisconsin 53226-0618

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	30 AUG 2007
Applicant's or agent's file reference 19799-PCT	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US 06/37085	22 September 2006 (22.09.2006)	20 October 2005 (20.10.2005)

International Patent Classification (IPC) or both national classification and IPC
IPC(8) - A61F 2/06 (2007.01)
USPC - 623/1.36, 623.1.11

Applicant Aptus Endosystems, Inc.

1. This opinion contains indications relating to the following items:

- [X] Box No. I Basis of the opinion
- [ ] Box No. II Priority
- [ ] Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- [ ] Box No. IV Lack of unity of invention
- [X] Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- [ ] Box No. VI Certain documents cited
- [ ] Box No. VII Certain defects in the international application
- [ ] Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US	Date of completion of this opinion	Authorized officer:
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	25 May 2007 (25.05.2007)	Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/237 (cover sheet) (April 2005)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 06/37085

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into _____ , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material

      ☐ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material

      ☐ on paper

      ☐ in electronic form

   c. time of filing/furnishing

      ☐ contained in the international application as filed

      ☐ filed together with the international application in electronic form

      ☐ furnished subsequently to this Authority for the purposes of search

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 06/37085

Box No. V **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1-29	YES
	Claims	NONE	NO
Inventive step (IS)	Claims	NONE	YES
	Claims	1-29	NO
Industrial applicability (IA)	Claims	1-29	YES
	Claims	NONE	NO

2. Citations and explanations:

Claims 1-8 lack an inventive step under PCT article 33(3) as being obvious over US 2003/0100943 A1 (Bolduc) in view of US 6,273,858 B1 to Fox et al. (hereinafter "Fox").

Regarding claim 1, directed to a system comprising a guide defining an access path into a vessel or hollow organ including a distal region and having a terminus and a fastener applier comprising a catheter sized and configured for introduction along the path and including an actuated member operable to generate an implantation force to implant at least one fastener into the tissue, the catheter including visible indicia to mark when the actuated member rests at a desired distance along the path short of the terminus of the distal region and out of contact with the tissue, Bolduc teaches a guided catheter system (para [0009]) with the guide component having a deflectable distal end tip (para [0013]). Bolduc also teaches apparatus for catheter implantation (para 0008]) and movable fastener appliers for attaching the catheter to the appropriate spot in proximity to the tissue (para [0012], [0013]) which is generally à vessel or organ lumen (para [0013]). Bolduc does not teach a means for visible indicia to mark the position of the catheter during implantation and use. Fox teaches catheters with visible markers to indicate depth of the position of an implanted catheter (col 6, ln 15-31). It would have been obvious to one of skill in the art to combine the teaching of Bolduc and Fox to produce a system comprising a guide defining an access path into a vessel or hollow organ including a distal region and having a terminus and a fastener applier comprising a catheter sized and configured for introduction along the path and including an actuated member operable to generate an implantation force to implant at least one fastener into the tissue, the catheter including visible indicia to mark when the actuated member rests at a desired distance along the path short of the terminus of the distal region and out of contact with the tissue.

Regarding claim 2, directed to the guide including a passage that defines the access path wherein the catheter is sized and configured for introduction along the path and wherein visible indicia mark when the actuated member rests at a desired distance inset within the passage between the terminus of the distal region and out of contact with the tissue, Bolduc as above teaches a guided catheter system (para [0009]) with the guide component having a deflectable distal end tip (para [0013]). Bolduc as above teaches apparatus for catheter implantation (para 0008]) and movable fastener appliers for attaching the catheter to the appropriate spot in proximity to the tissue (para [0012], [0013]) which is generally a vessel or organ lumen (para [0013]). Fox as above teaches catheters with visible markers to indicate depth of the position of an implanted catheter (col 6, ln 15-31). It would have been obvious to one of skill in the art to combine the teaching of Bolduc and Fox to produce a system including a passage that defines the access path wherein the catheter is sized and configured for introduction along the path and wherein visible indicia mark when the actuated member rests at a desired distance inset within the passage between the terminus of the distal region and out of contact with the tissue.

Regarding claim 3, directed to the passage comprising an interior lumen, Bolduc as above teaches apparatus for catheter implantation (para 0008]) and movable fastener appliers for attaching the catheter to the appropriate spot in proximity to the tissue (para [0012], [0013]) which is generally a vessel or organ lumen (para [0013]).

Regarding claim 4, directed to the access path including a proximal region having a visible entry to receive the catheter and wherein the indicia includes a visible marking on the catheter that visibly registers with the entry of the proximal region when the actuated member rests at a desired distance along the path short of the terminus of the distal region, Bolduc teaches a proximal region on a fastener for interacton with the catheter at the point of entry into the tissue (para [0040]). Fox as above teaches catheters with visible markers to indicate depth of the position of an implanted catheter (col 6, ln 15-31). It would have been obvious to one of skill in the art to combine the teaching of Bolduc and Fox to include including a proximal region having a visible entry to receive the catheter and wherein the indicia includes a visible marking on the catheter that visibly registers with the entry of the proximal region when the actuated member rests at a desired distance along the path short of the terminus of the distal region.

Regarding claim 5, directed to the distal region being deflectable, Bolduc as above teaches a guided catheter system (para [0009]) with the guide component having a deflectable distal end tip (para [0013]).

Regarding claim 6, directed to at least one fastener comprising a tissue-piercing fastener, Bolduc teaches a fastener which penertrates tissue (claim 14).

Regarding claim 7, directed to a helical fastener, Bolduc teaches helical fasteners (para [0012]).

----------SEE CONTINUATION SHEET----------

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 06/37085

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:

Regarding claim 8, directed to a guide defining an access path into a vessel or hollow organ including a distal region and having a terminus and a fastener applier comprising a catheter sized and configured for introduction along the path and including an actuated member operable to generate an implantation force to implant at least one fastener, the catheter including visible indicia to mark when the actuated member rests at a desired distance along the path short of the terminus of the distal region and out of contact with the tissue, instructions for using the guide and fastener applier comprising introducing the guide to a location at the target site within the vessel or hollow body organ where a diseased or damaged section exists, establishing the access path to a desired fastening site introducing the actuated member along the access path toward the terminus and viewing the visible indicia to detect when the actuated member rests at a desired distance along the path short of the terminus of the distal region, Bolduc as above teaches a guided catheter system (para [0009]) with the guide component having a deflectable distal end tip (para [0013]). Bolduc as above teaches apparatus for catheter implantation (para 0008]) and movable fastener appliers for attaching the catheter to the appropriate spot in proximity to the tissue (para [0012], [0013]) which is generally a vessel or organ lumen (para [0013]). Bolduc teaches the use of guided catheters for repair of aneurysms (para [0008]). Fox as above teaches catheters with visible markers to indicate depth of the position of an implanted catheter (col 6, ln 15-31). While neither Bolduc not Fox include instructions for the operation of the system, instructions for use of equipment are standard and non-inventive elements of equipment manufacture.

It would have been obvious to one of skill in the art to combine the teaching of Bolduc and Fox to provide a guide defining an access path into a vessel or hollow organ including a distal region and having a terminus and a fastener applier comprising a catheter sized and configured for introduction along the path and including an actuated member operable to generate an implantation force to implant at least one fastener, the catheter including visible indicia to mark when the actuated member rests at a desired distance along the path short of the terminus of the distal region and out of contact with the tissue, instructions for using the guide and fastener applier comprising introducing the guide to a location at the target site within the vessel or hollow body organ where a diseased or damaged section exists, establishing the access path to a desired fastening site introducing the actuated member along the access path toward the terminus and viewing the visible indicia to detect when the actuated member rests at a desired distance along the path short of the terminus of the distal region.

Claims 9-11 lack an inventive step under PCT article 33(3) as being obvious over Bolduc in view of Fox, as above, and further in view of US 2002/0156365 A1 (Tsekos).

Regarding claim 9, directed to a method comprising (i) a system of claim 1 or 8, (ii) introducing the guide to a target site within a vessel or hollow organ, (iii) establishing the access path to the desired fastening site at the target by manipulating the guide to orient the terminus with respect to the desired fastening site, (iv) introducing the actuated member along the access path toward the terminus and (v) viewing the visible indicia to detect when the actuated member rests at a desired distance along the path short of the terminus of the distal region, Bolduc as above teaches the use of guided catheters for repair of aneurysms (para [0008]). Bolduc also teaches apparatus for catheter implantation (para 0008]) and movable fastener appliers for attaching the catheter to the appropriate spot in proximity to the tissue (para [0012], [0013]) which is generally a vessel or organ lumen (para [0013]). Fox as above teaches catheters with visible markers to indicate depth of the position of an implanted catheter (col 6, ln 15-31). Neither Bolduc nor Fox teach actuators for orienting and manipulating the guide. Tsekos teaches actuators coupled to power drives for manipulating and positioning components of guide catheters (para [0069], [0070]). It would have been obvious to one of skill in the art to combine the teaching of Bolduc, Fox and Tsekos to introduce the guide to a target site within a vessel or hollow organ, establishing the access path to the desired fastening site at the target by manipulating the guide to orient the terminus with respect to the desired fastening site, introducing the actuated member along the access path toward the terminus and viewing the visible indicia to detect when the actuated member rests at a desired distance along the path short of the terminus of the distal region since introducing the actuated member along the access path would have been a matter of obvious design choice so as to provide an alternate and functionally equivalent design.

Regarding claim 10, directed to the further steps of (vi) advancing the actuated member to the terminus of the distal region and operating the actuated member to generate an implantation force to implant into the tissue at the desired fastening site, Bolduc as above teaches apparatus for catheter implantation (para 0008]) and movable fastener appliers for attaching the catheter to the appropriate spot in proximity to the tissue (para [0012], [0013]) which is generally a vessel or organ lumen (para [0013]). Tsekos as above teaches actuators coupled to power drives for manipulating and positioning components of guide catheters (para [0069], [0070]). It would have been obvious to one of skill in the art to combine the teaching of Bolduc, Fox and Tsekos to advance the actuated member to the terminus of the distal region and operating the actuated member to gsenerate an implantation force to implant into the tissue at the desired fastening site.

Regarding claim 11, directed to rotating the guide and/or deflecting the distal region, Bolduc as above teaches a guided catheter system (para [0009]) with the guide component having a deflectable distal end tip (para [0013]).

Claims 20-29 lack an inventive step under PCT article 33(3) as being obvious over Bolduc in view of US 2004/0054352 A1 to Adams et al. (hereinafter "Adams") and further in view of US 2004/0002731 A1 to Aganon et al. (hereinafter "Aganon").

----------SEE CONTINUATION SHEET----------

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

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Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:

Regarding claim 20 directed to a seal assembly with a first seal component with at least one guide tube formed therein, a second seal component with at least one guide tube formed therein, the second seal component registering with the first seal component with at least one guide tube in the second component coaxially aligned with at least with at least one guide tube in the first component, a septum between the first and second seal components the septum accommodating passage of a control filament from one of the coaxially aligned guide tubes through the septum to the other end of one of the coaxially aligned guide tubes, thereby providing a fluid seal for the control filament, Bolduc teaches seals for segregating parts of a guide catheter from body fluid (para [0005]). Bolduc does not teach a septum. Adams teaches a septum separating components of a catheter (para [0032]). Neither Bolduc nor Adams teach control filaments. Aganon teaches filaments or coils as part of a vaso-occlusive device (para [0007]). It would have been a matter of obvious design choice so as to provide an alternate and functionally equivalent design to position or align components. Therefore, it would have been obvious for the practitioner of skill in the art to be motivated to combine the teachings of Bolduc, Adams and Aganon to produce a seal assembly with a first seal component with at least one guide tube formed therein, a second seal component with at least one guide tube formed therein, the second seal component registering with the first seal component with at least one guide tube in the second component coaxially aligned with at least with at least one guide tube in the first component, a septum between the first and second seal components the septum accommodating passage of a control filament from one of the coaxially aligned guide tubes through the septum to the other end of one of the coaxially aligned guide tubes, thereby providing a fluid seal for the control filament.

Regarding claims 21 and 25, directed to the first or second seal being rigid (claim 21) or both the first or second seal being rigid (claim 25), Bolduc does not explicitly teach the physical properties of the seals. It would have been obvious for one of skill in the art to combine the teachings of Bolduc, Adams and Aganon to produce a seal from a rigid material that fits the needs of a seal assembly used in a guided catheter.

Regarding claims 22 and 26, directed to the septum comprising a soft material, Adams does not specify the physical nature of the septum except to indicate that it is capable of being pierced by a needle (para [0048]), implying a relatively soft material. It would have been obvious for one of skill in the art to combine the teachings of Bolduc, Adams and Aganon to use a soft material for a septum.

Regarding claims 23 and 27, directed to the septum comprising silicone rubber, Adams does not specify the nature of the material for a septum in a catheter assembly except to indicate that it is capable of being pierced by a needle (para [0048]), implying a relatively soft material. It would have been obvious for one of skill in the art to combine the teachings of Bolduc, Adams and Aganon to use a silicone rubber for a septum.

Regarding claims 24 and 28, directed to the septum comprising a gasket, Adams does not explicitly specify the shape of a septum. It would have been obvious for one of skill in the art to combine the teachings of Bolduc, Adams and Aganon to use a septum comprising a gasket since doing so would have been a matter of obvious design choice so as to provide an alternate and functionally equivalent design.

Regarding claim 29, directed to a catheter assembly including an operative element in use exposed to a body fluid, a control element, a seal assembly between the operative and control element, a control filament coupled to one end of the control element and a seal assembly between the control element and operative element through which the filament passes to prevent contact between body fluid and control element the seal assembly comprising a first seal component with at least one guide tube formed therein, a second seal component with at least one guide tube formed therein, the second seal component registering with the first seal component with at least one guide tube in the second component coaxially aligned with at least with at least one guide tube in the first component, a septum between the first and second seal components the septum accommodating passage of a control filament from one of the coaxially aligned guide tubes through the septum to the other end of one of the coaxially aligned guide tubes, thereby providing a fluid seal for the control filament, Bolduc as above teaches a guided catheter system (para [0009]) with the guide component having a deflectable distal end tip (para [0013]). Bolduc as above teaches seals for segregating parts of a guide catheter from body fluid (para [0005]). Aganon as above teaches filaments or coils as part of a vaso-occlusive device (para [0007]). Adams teaches a septum separating components of a catheter (para [0032]). It would have been obvious for one of skill in the art to combine the teachings of Bolduc, Adams and Aganon to assemble a catheter including an operative element in use exposed to a body fluid, a control element, a seal assembly between the operative and control element, a control filament coupled to one end of the control element and a seal assembly between the control element and operative element through which the filament passes to prevent contact between body fluid and control element the seal assembly comprising a first seal component with at least one guide tube formed therein, a second seal component with at least one guide tube formed therein, the second seal component registering with the first seal component with at least one guide tube in the second component coaxially aligned with at least with at least one guide tube in the first component, a septum between the first and second seal components the septum accommodating passage of a control filament from one of the coaxially aligned guide tubes through the septum to the other end of one of the coaxially aligned guide tubes, thereby providing a fluid seal for the control filament since positioning the components would have been a matter of obvious design choice so as to provide an alternate and functionally equivalent design.

Claims 12-19 lack an inventive step under PCT article 33(3) as being obvious over Bolduc in view of Tsekos and further in view of Adams and Aganon.

----------SEE CONTINUATION SHEET----------

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

Regarding claim 12, directed to an apparatus comprising a fastener applier comprising a catheter sized and configured for introduction along the path and including an actuated member operable in a first direction to load at least one fastener and in a second direction to generate an implantation force to implant the fastener within tissue, an electrically powered drive member coupled to the actuated member, a controller coupled to the drive member including a load state including means operable in response to an input command for delivering electric current to the drive member to drive the actuator member in a first direction to load a fastener, means for sensing electrical current delivered to the drive member while loading the fastener onto the member and means for terminating the electrical current when a prescribed amount of current is delivered to the drive member, terminating the load state, Bolduc as above teaches apparatus for catheter implantation (para 0008]) and movable fastener appliers for attaching the catheter to the appropriate spot in proximity to the tissue (para [0012], [0013]) which is generally a vessel or organ lumen (para [0013]). Tsekos as above teaches actuators coupled to power drives for manipulating and positioning components of guide catheters (para [0069], [0070]). Tsekos also teaches electrically powered drive members for driving the actuators (para [0071], [0075]) and controllers for automatically or manually manipulating the movable components of the guided catheter apparatus (para [0024], [0052]). Neither Bolduc nor Tsekos teach sensor means for detecting electrical current delivered to the drive member. Adams teaches implantable sensors for determining operation states of catheters (para [0033]). Neither Bolduc, Tsekos nor Adams teach delivery of electric current to the drive member. Aganon teaches the use of electrical current for driving movable components of guided catheter apparatus including movable fasteners (para [0075]). It would have been obvious for one of skill in the art to combine the teaching of Bolduc, Tsekos, Adams and Aganon to assemble an apparatus comprising a fastener applier comprising a catheter sized and configured for introduction along the path and including an actuated member operable in a first direction to load at least one fastener and in a second direction to generate an implantation force to implant the fastener within tissue, an electrically powered drive member coupled to the actuated member, a controller coupled to the drive member including a load state including means operable in response to an input command for delivering electric current to the drive member to drive the actuator member in a first direction to load a fastener, means for sensing electrical current delivered to the drive member while loading the fastener onto the member and means for terminating the electrical current when a prescribed amount of current is delivered to the drive member, terminating the load state. Operating the apparatus through the various states would have been a matter of obvious design choice given the interplay of elements so as to provide an alternate and functionally equivalent design.

Regarding claim 13, directed to the controller including an unwind state including means operative after termination of the load state for delivering electrical current to the drive member to drive the member in a second direction, means for sensing a period of operation of the member in the second direction sufficient to reduce torque windup on the driven member during the load state, means for terminating the electrical current when a prescribed amount of current is delivered to the drive member, terminating the unwind state, Tsekos as above teaches electrically powered drive members for driving the actuators (para [0071], [0075]) and controllers for automatically or manually manipulating the movable components of the guided catheter apparatus (para [0024], [0052]). Aganon as above teaches the use of electrical current for driving movable components of guided catheter apparatus including movable fasteners (para [0075]). It would have been obvious for one of skill in the art to combine the teaching of Bolduc, Tsekos, Adams and Aganon to produce an apparatus with a controller including an unwind state including means operative after termination of the load state for delivering electrical current to the drive member to drive the member in a second direction, means for sensing a period of operation of the member in the second direction sufficient to reduce torque windup on the driven member during the load state, means for terminating the electrical current when a prescribed amount of current is delivered to the drive member, terminating the unwind state. Operating the apparatus through the various states would have been a matter of obvious design choice given the interplay of elements so as to provide an alternate and functionally equivalent design.

Regarding claim 14, directed to the controller including a ready to apply state including means operative after termination of the unwind state to prompt a prescribed implant fastener input command, Tsekos as above teaches electrically powered drive members for driving the actuators (para [0071], [0075]) and controllers for automatically or manually manipulating the movable components of the guided catheter apparatus (para [0024], [0052]). It would have been obvious for one of skill in the art to combine the teaching of Bolduc, Tsekos, Adams and Aganon to produce an apparatus with a controller including a ready to apply state including means operative after termination of the unwind state to prompt a prescribed implant fastener input command. Operating the apparatus through the various states would have been a matter of obvious design choice given the interplay of elements so as to provide an alternate and functionally equivalent design.

----------SEE CONTINUATION SHEET----------

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

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Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:

Regarding claim 15, directed to the controller including a ready to apply state including means operable in response to the prescribed implant fastener input command for delivering electrical current to the drive member to drive the member in the second direction, means for sensing a partial period of operation of the driven member in the second direction less than a full period of operation sufficient to fully implant the fastener in tissue, means for terminating delivery of electrical current to the drive member after the partial period of operation and means for prompting either a continue implantation or terminate implantation command, Tsekos as above teaches electrically powered drive members for driving the actuators (para [0071], [0075]) and controllers for automatically or manually manipulating the movable components of the guided catheter apparatus (para [0024], [0052]). Adams as above teaches implantable sensors for determining operation states of catheters (para [0033]). Aganon teaches the use of electrical current for driving movable components of guided catheter apparatus including movable fasteners (para [0075]). It would have been obvious for one of skill in the art to combine the teaching of Bolduc, Tsekos, Adams and Aganon to assemble an apparatus with a controller including a ready to apply state including means operable in response to the prescribed implant fastener input command for delivering electrical current to the drive member to drive the member in the second direction, means for sensing a partial period of operation of the driven member in the second direction less than a full period of operation sufficient to fully implant the fastener in tissue, means for terminating delivery of electrical current to the drive member after the partial period of operation and means for prompting either a continue implantation or terminate implantation command. Operating the apparatus through the various states would have been a matter of obvious design choice given the interplay of elements so as to provide an alternate and functionally equivalent design.

Regarding claim 16, directed to the ready to apply state including means operative in response to the continue implantation command for delivering electrical current to the drive member to drive the member in the second direction sufficient to fully implant the fastener into the tissue for delivering electrical current to the drive member to drive the member in the first direction, means for sensing a partial period of operation of the driven member in the second direction less than a full period of operation sufficient to fully implant the fastener in tissue, Bolduc as above teaches apparatus for catheter implantation (para 0008]) and movable fastener appliers for attaching the catheter to the appropriate spot in proximity to the tissue (para [0012], [0013]) which is generally a vessel or organ lumen (para [0013]). Aganon as above teaches the use of electrical current for driving movable components of guided catheter apparatus including movable fasteners (para [0075]). Adams as above teaches implantable sensors for determining operation states of catheters (para [0033]). It would have been obvious for one of skill in the art to combine the teachings of Bolduc, Tsekos, Adams and Aganon to assemble an apparatus with the ready to apply state including means operative in response to the continue implantation command for delivering electrical current to the drive member to drive the member in the second direction sufficient to fully implant the fastener into the tissue for delivering electrical current to the drive member to drive the member in the first direction, means for sensing a partial period of operation of the driven member in the second direction less than a full period of operation sufficient to fully implant the fastener in tissue. Operating the apparatus through the various states would have been a matter of obvious design choice given the interplay of elements so as to provide an alternate and functionally equivalent design.

Regarding claim 17, directed to the ready to apply state including means operative in response to the terminate implantation command for delivering electrical current to the drive member to drive the member in the second direction, means for sensing a partial period of operation of the driven member in the first direction sufficient to fully withdraw the fastener from tissue, Bolduc as above teaches apparatus for catheter implantation (para 0008]) and movable fastener appliers for attaching the catheter to the appropriate spot in proximity to the tissue (para [0012], [0013]) which is generally a vessel or organ lumen (para [0013]). Aganon as above teaches the use of electrical current for driving movable components of guided catheter apparatus including movable fasteners (para [0075]). Adams as above teaches implantable sensors for determining operation states of catheters (para [0033]). It would have been obvious for one of skill in the art to combine the teachings of Bolduc, Tsekos, Adams and Aganon to assemble an apparatus with the ready to apply state including means operative in response to the terminate implantation command for delivering electrical current to the drive member to drive the member in the second direction, means for sensing a partial period of operation of the driven member in the first direction sufficient to fully withdraw the fastener from tissue. Operating the apparatus through the various states would have been a matter of obvious design choice given the interplay of elements so as to provide an alternate and functionally equivalent design.

Regarding claim 18, directed to a method comprising (i) the apparatus as defined in claim 12, (ii) operating the fastener applier in the load state to load a fastener onto the drive member and (iii) introducing the fastener applier to a location at the target site within a vessel or hollow organ where a diseased or damaged section exists, Bolduc as above teaches apparatus for catheter implantation (para 0008]) and movable fastener appliers for attaching the catheter to the appropriate spot in proximity to the tissue (para [0012], [0013]) which is generally a vessel or organ lumen (para [0013]). Bolduc teaches the use of guided catheters for repair of aneurysms (para [0008]). It would have been obvious for one of skill in the art to combine the teaching of Bolduc, Tsekos, Adams and Aganon to operate the fastener applier in the load state to load a fastener onto the drive member and introduce the fastener applier to a location at the target site within a vessel or hollow organ where a diseased or damaged section exists.

Regarding claim 19, directed to a method comprising (i) the apparatus as defined in claim 13, (ii) operating the fastener applier in the load and unwind states to load a fastener onto the drive member and (iii) introducing the fastener applier to a location at the target site within a vessel or hollow organ where a diseased or damaged section exists, Bolduc as above teaches apparatus for catheter implantation (para 0008]) and movable fastener appliers for attaching the catheter to the appropriate spot in proximity to the tissue (para [0012], [0013]) which is generally a vessel or organ lumen (para [0013]). Bolduc teaches the use of guided catheters for repair of aneurysms (para [0008]). It would have been obvious for one of skill in the art to combine the teaching of Bolduc, Tsekos, Adams and Aganon to operate the fastener applier in the load and unwind states to load a fastener onto the drive member and introduce the fastener applier to a location at the target site within a vessel or hollow organ where a diseased or damaged section exists.

Claims 1-29 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used in industry.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 19799-PCT	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/US06/37085	International filing date *(day/month/year)* 22 September 2006 (22.09.2006)	Priority date *(day/month/year)* 20 October 2005 (20.10.2005)
International Patent Classification (IPC) or national classification and IPC IPC: **A61F 2/06**(2006.01) USPC: 623/1.36;623/1.11		
Applicant APTUS ENDOSYSTEMS, INC.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 9 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☐ *(sent to the applicant and to the International Bureau)* a total of ___ sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) _____ , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:
   - ☒ Box No. I Basis of the report
   - ☐ Box No. II Priority
   - ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - ☐ Box No. IV Lack of unity of invention
   - ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - ☐ Box No. VI Certain documents cited
   - ☐ Box No. VII Certain defects in the international application
   - ☐ Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
17 May 2007 (17.05.2007)	22 July 2008 (22.07.2008)
Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Authorized officer ALLAN SHOAP Telephone No. 571-272-3700

Form PCT/IPEA/409 (cover sheet)(April 2007)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
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Box No. I Basis of the report

1. With regard to the **language**, this report is based on:

☒ the international application in the language in which it was filed.

☐ a translation of the international application into English, which is the language of a translation furnished for the purposes of:

☐ international search (under Rules 12.3(a) and 23.1(b))

☐ publication of the international application (under Rule 12.4(a))

☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ the international application as originally filed/furnished

☒ the description:
pages 1-52 as originally filed/furnished
pages* NONE received by this Authority on
pages* NONE received by this Authority on

☒ the claims:
pages 53-59 as originally filed/furnished
pages* NONE as amended (together with any statement) under Article 19
pages* NONE received by this Authority on
pages* NONE received by this Authority on

☒ the drawings:
pages 1-23 as originally filed/furnished
pages* NONE received by this Authority on
pages* NONE received by this Authority on

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages
☐ the claims, Nos.
☐ the drawings, sheets/figs
☐ the sequence listing (*specify*):
☐ any table(s) related to the sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages
☐ the claims, Nos.
☐ the drawings, sheets/figs
☐ the sequence listing (*specify*):
☐ any table(s) related to the sequence listing (*specify*):

5. ☐ This report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 70.2(e)).

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 1-29	YES
	Claims NONE	NO
Inventive Step (IS)	Claims NONE	YES
	Claims 1-2	NO
Industrial Applicability (IA)	Claims 1-29	YES
	Claims NONE	NO

2. Citations and Explanations (Rule 70.7)
Please See Continuation Sheet

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US06/37085

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**

Continuation of:

V. 2. Citations and Explanations:

Claims 1-8 lack an inventive step under PCT article 33(3) as being obvious over BOLDUC in view of FOX al. (hereinafter "Fox").

Regarding claim 1, directed to a system comprising a guide defining an access path into a vessel or hollow organ including a distal region and having a terminus and a fastener applier comprising a catheter sized and configured for introduction along the path and including an actuated member operable to generate an implantation force to implant at least one fastener into the tissue, the catheter including visible indicia to mark when the actuated member rests at a desired distance along the path short of the terminus of the distal region and out of contact with the tissue, Bolduc teaches a guided catheter system (para [0009]) with the guide component having a deflectable distal end tip (para [0013]). Bolduc also teaches apparatus for catheter implantation (para 0008]) and movable fastener appliers for attaching the catheter to the appropriate spot in proximity to the tissue (para [0012], [0013]) which is generally a vessel or organ lumen (para [0013]). Bolduc does not teach a means for visible indicia to mark the position of the catheter during implantation and use. Fox teaches catheters with visible markers to indicate depth of the position of an implanted catheter (col 6, ln 15-31). It would have been obvious to one of skill in the art to combine the teaching of Bolduc and Fox to produce a system comprising a guide defining an access path into a vessel or hollow organ including a distal region and having a terminus and a fastener applier comprising a catheter sized and configured for introduction along the path and including an actuated member operable to generate an implantation force to implant at least one fastener into the tissue, the catheter including visible indicia to mark when the actuated member rests at a desired distance along the path short of the terminus of the distal region and out of contact with the tissue.

Regarding claim 2, directed to the guide including a passage that defines the access path wherein the catheter is sized and configured for introduction along the path and wherein visible indicia mark when the actuated member rests at a desired distance inset within the passage between the terminus of the distal region and out of contact with the tissue, Bolduc as above teaches a guided catheter system (pare [0009]) with the guide component having a deflectable distal end tip (para [0013]). Botduc as above teaches apparatus for catheter

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Supplemental Box

implantation (para 0008]) and movable fastener appliers for attaching the catheter to the appropriate spot in proximity to the tissue (para [0012], [0013]) which is generally a vessel or organ lumen (para [0013]). Fox as above teaches catheters with visible markers to indicate depth of the position of an implanted catheter (col 6, In 15-31). It would have been obvious to one of skill in the art to combine the teaching of Bolduc and Fox to produce a system including a passage that defines the access path wherein the catheter is sized and configured for introduction along the path and wherein visible indicia mark when the actuated member rests at a desired distance inset within the passage between the terminus of the distal region and out of contact with the tissue.

Regarding claim 3, directed to the passage comprising an interior lumen, Bolduc as above teaches apparatus for catheter implantation (para 0008]) and movable fastener appliers for attaching the catheter to the appropriate spot in proximity to the tissue (pare [0012], [0013]) which is generally a vessel or organ lumen (para [0013]).

Regarding claim 4, directed to the access path including a proximal region having a visible entry to receive the catheter and wherein the indicia includes a visible marking on the catheter that visibly registers with the entry of the proximal region when the actuated member rests at a desired distance along the path short of the terminus of the distal region, Bolduc teaches a proximal region on a fastener for interacton with the catheter at the point of entry into the tissue (para [0040]). Fox as above teaches catheters with visible markers to indicate depth of the position of an implanted catheter (col 6, In 15-31). It would have been obvious to one of skill in the art to combine the teaching of Bolduc and Fox to include including a proximal region having a visible entry to receive the catheter and wherein the indicia includes a visible marking on the catheter that visibly registers with the entry of the proximal region when the actuated member rests at a desired distance along the path short of the terminus of the distal region.

Regarding claim 5, directed to the distal region being deflectable, Bolduc as above teaches a guided catheter system (para [0009]) with the guide component having a deflectable distal end tip (pare [0013]).

Regarding claim 6, directed to at least one fastener comprising a tissue-pieming fastener, Bolduc teaches a fastener which penertrates tissue (claim 14).

Regarding claim 7, directed to a helical fastener, Bolduc teaches helical fasteners (pare [0012]).

Regarding claim 8, directed to a guide defining an access path into a vessel or hollow organ including a distal region and having a terminu~ and a fastener applier comprising a catheter sized and configured for introduction along the path and including an actuated member operable to generate an implantation force to implant at least one fastener, the catheter including visible indicia to mark when the actuated member rests at a desired distance along the path short of the terminus of the distal region and out of contact with the tissue, instructions for using the guide and fastener applier compdsing introducing the guide to a location at the target site within the vessel or hollow body organ where a diseased or damaged section exists, establishing the access path to a desired fastening site introducing the actuated member along the access path toward the terminus and viewing the visible indicia to detect when the actuated member rests at a desired distance along the path short of the terminus of the distal region, Bolduc as above teaches a guided catheter system (para [0009)) with the guide component having a deflectable distal end tip (para [0013]). Bolduc as above teaches apparatus for catheter implantation (para 0008]) and movable fastener appliers for attaching the catheter to the appropriate spot in proximity to the tissue (para [0012], [0013]) whict is generally a vessel or organ lumen (pare [0013]). Bolduc teaches the use of guided catheters for repair of aneurysms (para [0008]). Fox as above teaches catheters with visible markers to indicate depth of the position of an implanted catheter (col 6, In 15-31). While neither Bolduc not Fox include instructions for the operation of the system, instructions for use of equipment are standard and non-inventive elements of equipment manufacture.

It would have been obvious to one of skill in the art to combine the teaching of Bolduc and Fox to provide a guide defining an access path into a vessel or hollow organ including a distal region and having a terminus and a fastener applier comprising a catheter sized and configured for introduction along the path and including an actuated member operable to generate an implantation force to implant at least one fastener, the catheter including visible indicia to mark when the actuated member rests at a desired distance along the path short of the terminus of the distal region and out of contact with the tissue, instructions for using the guide and fastener applier compdsing introducing the guide to a location at the target site within the vessel or hollow body organ where a diseased or damaged section exists, establishing the access path to a desired fastening site introducing the actuated member along the access path toward the terminus and viewing the visible indicia to detect when the actuated member rests at a desired distance along the path short of the terminus of the distal region.

Claims 9-11 lack an inventive step under PCT article 33(3) as being obvious over BOLDUC in view of FOX, as above, and further in view of TSEKOS.

Regarding claim 9, directed to a method comprising (i) a system of claim 1 or 8, (ii) introducing the guide to a target site within a vessel or hollow organ, (iii) establishing the access path to the desired fastening site at the target by manipulating the guide to orient the terminus with respect to the desired fastening site, (iv) introducing the actuated member along the access path toward the terminus and (v) viewing the visible indicia to detect when the actuated member rests at a desired distance along the path short of the terminus of the distal region, Bolduc as above teaches the use of guided catheters for repair of aneurysms (pare [0008]). Bolduc also teaches apparatus for catheter implantation (pare 0008]) and movable fastener appliers for attaching the catheter to the appropriate spot in proximity to the tissue (para [0012], [0013]) which is generally a vessel or organ lumen (pare [0013]). Fox as above teaches catheters with visible markers

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to indicate depth of the position of an implanted catheter (col 6, ln 15-31). Neither Bolduc nor Fox teach actuators for orienting and manipulating the guide. Tsekos teaches actuators coupled to power drives for manipulating and positioning components of guide catheters (para [0069], [0070]). It would have been obvious to one of skill in the art to combine the teaching of Bolduc, Fox and Tsekos to introduce the guide to a target site within a vessel or hollow organ, establishing the access path to the desired fastening site at the target by manipulating the guide to orient the terminus with respect to the desired fastening site, introducing the actuated member along the access path toward the terminus and viewing the visible indicia to detect when the actuated member rests at a desired distance along the path short of the terminus of the distal region since introducing the actuated member along the access path would have been a matter of obvious design choice so as to provide an alternate and functionally equivalent design.

Regarding claim 10, directed to the further steps of (vi) advancing the actuated member to the terminus of the distal region and operating the actuated member to generate an implantation force to implant into the tissue at the desired fastening site, Bolduc as above teaches apparatus for catheter implantation (para 0008]) and movable fastener appliers for attaching the catheter to the appropriate spot in proximity to the tissue (para [0012], [0013]) which is generally a vessel or organ lumen (para [0013]). Tsekos as above teaches actuators coupled to power drives for manipulating and positioning components of guide catheters (pare [0069], [0070]). It would have been obvious to one of skill in the art to combine the teaching of Bolduc, Fox and Tsekos to advance the actuated member to the terminus of the distal region and operating the actuated member to gsenerate an implantation force to implant into the tissue at the desired fastening site.

Regarding claim 11, directed to rotating the guide and/or deflecting the distal region, Bolduc as above teaches a guided catheter system (pare [0009]) with the guide component having a deflectable distal end tip (pare [0013]).

Claims 20-29 lack an invent!ve step under PCT article 33(3) as being obvious over BOLDUC in view of ADAMS et al. (hereinafter "Adams") and further in view of AGANON et al. (hereinafter "Aganon").

Regarding claim 20 directed to a seal assembly with a first seal component with at least one guide tube formed therein, a second seal component with at least one guide tube formed therein, the second seal component registering with the first seal component with at least one guide tube in the second component coaxially aligned with at least with at least one guide tube in the first component, a septum between the first and second seal components the septum accommodating passage of a control filament from one of the coaxially aligned guide tubes through the septum to the other end of one of the coaxially aligned guide tubes, thereby providing a fluid seal for the control filament, Bolduc teaches seals for segregating parts of a guide catheter from body fluid (para [0005]). Bolduc does not teach a septum. Adams teaches a septum separating components of a catheter (para [0032]). Neither Bolduc nor Adams teach control filaments. Aganon teaches filaments or coils as part of a vase-occlusive device (para [0007]). It would have been a matter of obvious design choice so as to provide an alternate and functionally equivalent design to position or align components. Therefore, it would have been obvious for the practitioner of skill in the art to be motivated to combine the teachings of Bolduc, Adams and Aganon to produce a seal assembly with a first seal component with at least one guide tube formed therein, a second seal component with at least one guide tube formed therein, the second seal component registering with the first seal component with at least one guide tube in the second component coaxially aligned with at least with at least one guide tube in the first component, a septum between the first and second seal components the septum accommodating passage of a control filament from one of the coaxially aligned guide tubes through the septum to the other end of one of the coaxially aligned guide tubes, thereby providing a fluid seal for the control filament.

Regarding claims 21 and 25, directed to the first or second seal being rigid (claim 21) or both the first or second seal being rigid (claim 25), Bolduc does not explicitly teach the physical properties of the seals. It would have been obvious for one of skill in the art to combine the teachings of Bolduc, Adams and Aganon to produce a seal from a rigid material that fits the needs of a seal assembly used in a guided catheter.

Regarding claims 22 and 26, directed to the septum comprising a soft material, Adams does not specify the physical nature of the septum except to indicate that it is capable of being pierced by a needle (para [0048]), implying a relatively soft material. It would have been obvious for one of skill in the art to combine the teachings of Bolduc, Adams and Aganon to use a soft material for a septum.

Regarding claims 23 and 27, directed to the septum comprising silicone rubber, Adams does not specify the nature of the material for a septum in a catheter assembly except to indicate that it is capable of being pierced by a needle (para [0048]), implying a relatively soft material. It would have been obvious for one of skill in the art to combine the teachings of Bolduc, Adams and Aganon to use a silicone rubber for a septum.

Regarding claims 24 and 28, directed to the septum comprising a gasket, Adams does not explicitly specify the shape of a septum. It would have been obvious for one of skill in the art to combine the teachings of Bolduc, Adams and Aganon to use a septum comprising a gasket since doing so would have been a matter of obvious design choice so as to provide an alternate and functionally equivalent design.

Regarding claim 29, directed to a catheter assembly including an operative element in use exposed to a body fluid, a control element, a seal assembly between the operative and control element, a control filament coupled to one end of the control element and a seal assembly between the control element and operative element through which the filament passes to prevent contact between body fluid and control element the seal assembly comprising a first seal component with at least one guide tube formed therein, a second seal component with at least one guide tube formed therein, the second seal component registering with the first seal component with at least

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one guide tube in the second component coaxially aligned with at least with at least one guide tube in the first component, a septum between the first and second seal components the septum accommodating passage of a control filament from one of the coaxially aligned guide tubes through the septum to the other end of one of the coaxially aligned guide tubes, thereby providing a fluid seal for the control filament, Bolduc as above teaches a guided catheter system (para [0009]) with the guide component having a deflectable distal end tip (para [0013]). Bolduc as above teaches seals for segregating parts of a guide catheter from body fluid (para [0005]). Aganon as above teaches filaments or coils as part of a vase-occlusive device (para [0007]). Adams teaches a septum separating components of a catheter (para [0032]). It would have been obvious for one of skill in the art to combine the teachings of Bolduc, Adams and Aganon to assemble a catheter including an operative element in use exposed to a body fluid, a control element, a seal assembly between the operative and control element, a control filament coupled to one end of the control element and a seal assembly between the control element and operative element through which the filament passes to prevent contact between body fluid and control element the seal assembly comprising a first seal component with at least one guide tube formed therein, a second seal component with at least one guide tube formed therein, the second seal component registering with the first seal component with at least one guide tube in the second component coaxially aligned with at least with at least one guide tube in the first component, a septum between the first and second seal components the septum accommodating passage of a control filament from one of the coaxially aligned guide tubes through the septum to the other end of one of the coaxially aligned guide tubes, thereby providing a fluid seal for the control filament since positioning the components would have been a matter of obvious design choice so as to provide an alternate and functionally equivalent design.

Claims 12-19 lack an inventive step under PCT article 33(3) as being obvious over Bolduc in view of Tsekos and further in view of Adams and Aganon.

Regarding claim 12, directed to an apparatus comprising a fastener applier comprising a catheter sized and configured for introduction along the path and including an actuated member operable in a first direction to load at least one fastener and in a second direction to generate an implantation force to implant the fastener within tissue, an electrically powered drive member coupled to the actuated member, a controller coupled to the drive member including a load state including means operable in response to an input command for delivering electric current to the drive member to drive the actuator member in a first direction to load a fastener, means for sensing electrical current delivery to the drive member when loading the fastener onto the member and means for terminating the electrical current when a prescribed amount of current is delivered to the drive member, terminating the load state, Bolduc as above teaches apparatus for catheter implantation (para 0008]) and movable fastener appliers for attaching the catheter to the appropriate spot in proximity to the tissue (para [0012], [0013]) which is generally a vessel or organ lumen (para [0013]). Tsekos as above teaches actuators coupled to power drives for manipulating and positioning components of guide catheters (para [0069], [0070]). Tsekos also teaches electrically powered drive members for driving the actuators (para [0071], [0075]) and controllers for automatically or manually manipulating the movable components of the guided catheter apparatus (para [0024], [0052]). Neither Bolduc nor Tsekos teach sensor means for detecting electrical current delivered to the drive member. Adams teaches implantable sensors for determining operation states of catheters (para [0033]). Neither Bolduc, Tsekos nor Adams teach delivery of electric current to the drive member. Aganon teaches the use of electrical current for driving movable components of guided catheter apparatus including movable fasteners (para [0075]). It would have been obvious for one of skill in the art to combine the teaching of Bolduc, Tsekos, Adams and Aganon to assemble an apparatus comprising a fastener applier comprising a catheter sized and configured for introduction along the path and including an actuated member operable in a first direction to load at least one fastener and in a second direction to generate an implantation force to implant the fastener within tissue, an electrically powered drive member coupled to the actuated member, a controller coupled to the drive member including a load state including means operable in response to an input command for delivering electric current to the drive member to drive the actuator member in a first direction to load a fastener, means for sensing electrical current delivered to the drive member while loading the fastener onto the member and means for terminating the electrical current when a prescribed amount of current is delivered to the drive member, terminating the load state. Operating the apparatus through the various states would have been a matter of obvious design choice given the interplay of elements so as to provide an alternate and functionally equivalent design.

Regarding claim 13, directed to the controller including an unwind state including means operative after termination of the load state for delivering electrical current to the drive member to drive the member in a second direction, means for sensing a period of operation of the member in the second direction sufficient to reduce torque windup on the driven member during the load state, means for terminating the electrical current when a prescribed amount of current is delivered to the drive member, terminating the unwind state, Tsekos as above teaches electrically powered drive members for driving the actuators (para [0071], [0075]) and controllers for automatically or manually manipulating the movable components of the guided catheter apparatus (para [0024], [0052]). Aganon as above teaches the use of electrical current for driving movable components of guided catheter apparatus including movable fasteners (para [0075]). It would have been obvious for one of skill in the art to combine the teaching of Bolduc, Tsekos, Adams and Aganon to produce an apparatus with a controller including an unwind state including means operative after termination of the load state for delivering electrical current to the drivq member to drive the member in a second direction, means for sensing a period of operation of the member in the second direction sufficient to reduce torque windup on the driven member during the load state, means for terminating the electrical current when a prescribed amount of current is delivered to the drive member, terminating the unwind state. Operating the apparatus through the various states would have been a matter of obvious design choice given the interplay of elements so as to provide an alternate and functionally equivalent design.

Regarding claim 14, directed to the controller including a ready to apply state including means operative after termination of the unwind state to prompt a prescribed implant fastener input command, Tsekos as above teaches electrically powered drive members for driving the actuators (para [0071], [0075]) and controllers for automatically or manually manipulating the movable components of the guided

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catheter apparatus (para [0024], [0052]). It would have been obvious for one of skill in the art to combine the teaching of Bolduc, Tsekos, Adams and Aganon to produce an apparatus with a controller including a ready to apply state including means operative after termination of the unwind state to prompt a prescribed implant fastener input command. Operating the apparatus through the various states would have been a matter of obvious design choice given the interplay of elements so as to provide an alternate and functionally equivalent design.

Regarding claim 15, directed to the controller including a ready to apply state including means operable in response to the prescribed implant fastener input command for delivering electrical current to the drive member to drive the member in the second direction, means for sensing a partial period of operation of the driven member in the second direction less than a full period of operation sufficient to fully implant the fastener in tissue, means for terminating delivery of electrical current to the drive member after the partial period of operation and means for prompting either a continue implantation or terminate implantation command, Tsekos as above teaches electrically powered drive members for driving the actuators (para [0071], [0075]) and controllers for automatically or manually manipulating the movable components of the guided catheter apparatus (para [0024], [0052]). Adams as above teaches implantable sensors for determining operation states of catheters (para [0033]). Aganon teaches the use of electrical current for driving movable components of guided catheter apparatus including movable fasteners (para [0075]). it would have been obvious for one of skill in the art to combine the teaching of Bolduc, Tsekos, Adams and Aganon to assemble an apparatus with a controller including a ready to apply state including means operable in response to the prescribed implant fastener input command for delivering electrical current to the drive member to drive the member in the second direction, means for sensing a partial period of operation of the driven member in the second direction less than a full period of operation sufficient to fully implant the fastener in tissue, means for terminating delivery of electrical current to the drive member after the partial period of operation and means for prompting either a continue implantation or terminate implantation command. Operating the apparatus through the various states would have been a matter of obvious design choice given the interplay of elements so as to provide an alternate and functionally equivalent design.

Regarding claim 16, directed to the ready to apply state including means operative in response to the continue implantation command for delivering electrical current to the drive member to drive the member in the second direction sufficient to fully implant the fastener into the tissue for delivering electrical current to the drive member to drive the member in the first direction, means for sensing a partial period of operation of the driven member in the second direction less than a full period of operation sufficient to fully implant the fastener in tissue, Bolduc as above teaches apparatus for catheter implantation (pars 0008]) and movable fastener appliers for attaching the catheter to the appropriate spot in proximity to the tissue (para [0012], [0013]) which is generally a vessel or organ lumen (para [0013]). Aganon as above teaches the use of electrical current for driving movable components of guided catheter apparatus including movable fasteners (para [0075]). Adams as above teaches implantable sensors for determining operation states of catheters (para [0033]). It would have been obvious for one of skill in the art to combine the teachings of Bolduc, Tsekos, Adams and Aganon to assemble an apparatus with the ready to apply state including means operative in response to the continue implantation command for delivering electrical current to the drive member to drive the member in the second direction sufficient to fully implant the fastener into the tissue for delivering electrical current to the drive member to drive the member in the first direction, means for sensing a partial period of operation of the driven member in the second direction less than a full period of operation sufficient to fully implant the fastener in tissue. Operating the apparatus through the various states would have been a matter of obvious design choice given the interplay of elements so as to provide an alternate and functionally equivalent design.

Regarding claim 17, directed to the ready to apply state including means operative in response to the terminate implantation command for delivering electrical current to the drive member to drive the member in the second direction, means for sensing a partial period of operation of the driven member in the first direction sufficient to fully withdraw the fastener from tissue, Bolduc as above teaches apparatus for catheter implantation (para 0008]) and movable fastener appliers for attaching the catheter to the appropriate spot in proximity to the tissue (para [0012], [0013]) which is generally a vessel or organ lumen (para [0013]). Aganon as above teaches the use of electrical current for driving movable components of guided catheter apparatus including movable fasteners (para [0075]). Adams as above teaches implantable sensors for determining operation states of catheters (para [0033]). It would have been obvious for one of skill in the art to combine the teachings of Bolduc, Tsekos, Adams and Aganon to assemble an apparatus with the ready to apply state including means operative in response to the terminate implantation command for delivering electrical current to the drive member to drive the member in the second direction, means for sensing a partial period of operation of the driven member in the first direction sufficient to fully withdraw the fastener from tissue. Operating the apparatus through the various states would have been a matter of obvious design choice given the interplay of elements so as to provide an alternate and functionally equivalent design.

Regarding claim 18, directed to a method comprising (i) the apparatus as defined in claim 12, (ii) operating the fastener applier in the load state to load a fastener onto the drive member and (iii) introducing the fastener applier to a location at the target site within a vessel or hollow organ where a diseased or damaged section exists, Bolduc as above teaches apparatus for catheter implantation (para 0008]) and movable fastener appliers for attaching the catheter to the appropriate spot in proximity to the tissue (para [0012], [0013]) which is generally a vessel or organ lumen (para [0013]). Bolduc teaches the use of guided catheters for repair of aneurysms (para [0008]). It would have been obvious for one of skill in the art to combine the teaching of Bolduc, Tsekos, Adams and Aganon to operate the fastener applier in the load state to load a fastener onto the drive member and introduce the fastener applier to a location at the target site within a vessel or hollow organ where a diseased or damaged section exists.

Regarding claim 19, directed to a method comprising (i) the apparatus as defined in claim 13, (ii) operating the fastener applier in the load and unwind states to load a fastener onto the drive member and (iii) introducing the fastener applier to a location at the target site

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within a vessel or hollow organ where a diseased or damaged section exists, Bolduc as above teaches apparatus for catheter implantation (para 0008]) and movable fastener appliers for attaching the catheter to the appropriate spot in proximity to the tissue (para [0012], [0013]) which is generally a vessel or organ lumen (para [0013]). Bolduc teaches the use of guided catheters for repair of aneurysms (para [0008]). It would have been obvious for one of skill in the art to combine the teaching of Bolduc, Tsekos, Adams and Aganon to operate the fastener applier in the load and unwind states to load a fastener onto the drive member and introduce the fastener applier to a location at the target site within a vessel or hollow organ where a diseased or damaged section exists.

Claims 1-29 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used in industry.

---------- NEW CITATIONS ----------

NONE

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To:
JOSEPH A. KROMHOLZ
RYAN KROMHOLZ & MANION, S.C.
P.O.BOX 26618
MILWAUKEE, WI 53226-0618

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

	Date of mailing *(day/month/year)* 11 DEC 2009
Applicant's or agent's file reference 20397-C PCT	**FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/US 09/05604	International filing date *(day/month/year)* 14 October 2009 (14.10.2009)
Applicant APTUS ENDOSYSTEMS, INC.	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

   Filing of amendments and statement under Article 19:
   The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

   When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

   Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes 1211 Geneva 20, Switzerland, Facsimile No.: +41 22 338 8270

   For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

   ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

   ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

   Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90*bis*.1 and 90*bis*.3, respectively, before the completion of the technical preparations for international publication.

   The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

   Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

   In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

   See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/220 (January 2004)

(See notes on accompanying sheet)

PATENT COOPERATION TREATY

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INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 20397-C PCT	**FOR FURTHER ACTION**	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/US 09/05604	International filing date *(day/month/year)* 14 October 2009 (14.10.2009)	(Earliest) Priority Date *(day/month/year)* 16 October 2008 (16.10.2008)
Applicant APTUS ENDOSYSTEMS, INC.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 2 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

   a. With regard to the **language**, the international search was carried out on the basis of:

   ☒ the international application in the language in which it was filed.

   ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

   b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).

   c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (see Box No. II).

3. ☐ **Unity of invention is lacking** (see Box No. III).

4. With regard to the **title**,

   ☒ the text is approved as submitted by the applicant.

   ☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

   ☒ the text is approved as submitted by the applicant.

   ☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

   a. the figure of the **drawings** to be published with the abstract is Figure No. 13C

   ☐ as suggested by the applicant.

   ☒ as selected by this Authority, because the applicant failed to suggest a figure.

   ☐ as selected by this Authority, because this figure better characterizes the invention.

   b. ☐ none of the figures is to be published with the abstract.

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A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61F 2/06 (2009.01)
USPC - 623/1.11
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
623/1.11

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
128/898, 604/96.01; 623/1.15, 1.2, 1.3, 1.32

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PubWest, Google
Search Terms Used: Implant, lumen, steerable, catheter, guide, stapling or anchoring, fasteners, self-expanding or balloon expandable, bend , deflect.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2008/0065189 A1 (Bolduc) 13 March 2008 (13.03.2008), abstract, para [0033]-[0037], Figs. 9, 15.	1-22
Y	US 2007/0073389 A1 (Bolduc et al.) 29 March 2007 (29.03.2007), para [0008], [0054], [0115], [0161], Fig. 7A	1-22

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
1 December 2009 (01.12.2009)	11 DEC 2009
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (July 2009)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: JOSEPH A. KROMHOLZ
RYAN KROMHOLZ & MANION, S.C.
P.O.BOX 26618
MILWAUKEE, WI 53226-0618

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	11 DEC 2009
Applicant's or agent's file reference 20397-C PCT	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US 09/05604	14 October 2009 (14.10.2009)	16 October 2008 (16.10.2008)

International Patent Classification (IPC) or both national classification and IPC
IPC(8) - A61F 2/06 (2009.01)
USPC - 623/1.11

Applicant APTUS ENDOSYSTEMS, INC.

1. This opinion contains indications relating to the following items:

- [X] Box No. I Basis of the opinion
- [ ] Box No. II Priority
- [ ] Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- [ ] Box No. IV Lack of unity of invention
- [X] Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- [ ] Box No. VI Certain documents cited
- [ ] Box No. VII Certain defects in the international application
- [ ] Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US	Date of completion of this opinion	Authorized officer:
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	1 December 2009 (01.12.2009)	Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/237 (cover sheet) (July 2009)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
T/US 09/05604

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed.

   ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing filed or furnished:

   a. (means)

      ☐ on paper

      ☐ in electronic form

   b. (time)

      ☐ in the international application as filed

      ☐ together with the international application in electronic form

      ☐ subsequently to this Authority for the purposes of search

4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 09/05604

Box No. V **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1-22	YES
	Claims	None	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-22	NO
Industrial applicability (IA)	Claims	1-22	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1-22 lack an inventive step under PCT Article 33(3) as being obvious over US 2008/0065189 A1 to Bolduc (hereinafter Bolduc189) in view of US 2007/0073389 A1 to Bolduc et al. (hereinafter Bolduc389).

As per claim 1, Bolduc189 teaches a steerable guide catheter comprising: a first guide tube having a length and defining an open interior lumen, the first guide tube lumen adapted for accommodating passage of an operative endovascular tool (abstract, para [0035], Fig. 15), and a handle assembly comprising: a first deflecting means coupled to a distal end region of the first guide tube to apply a deflecting force to bend the distal end region of (para [0033]; Fig. 9. In one embodiment the control assembly 21 features a movable wheel or lever 22, which deflects the distal tip 23 of the directing device 18 to the desired location.), the first guide tube the first deflecting means adapted to bend the distal end region in a first articulated position (para [0033]), however, does not specifically disclose wherein a second guide tube having a length and defining an open interior lumen, the second guide tube lumen adapted for accommodating the first guide tube, and a second deflecting means coupled to a distal end region of the second guide tube to apply a deflecting force to bend the distal end region of the second guide tube, the second deflecting means adapted to bend the distal end region in a second articulated position. Bolduc389 teaches wherein a system comprising a guide defining an access path into a vessel or hollow body organ and a fastener applier comprising a catheter sized and configured for introduction along the access path to a site targeted for implantation of at least one fastener (para [0008]) and wherein the distal portion of the guide tube 164 can be deflected in one direction and straightened by a steering wire coupled to a rotational deflector knob 170 on the handle 166 (para [0115]; Fig. 7A). It would have been obvious to one of ordinary skill in the art to use the teaching of Bolduc389 and utilize a second guide tube having a length and defining an open interior lumen, a second deflecting means coupled to a distal end region of the second guide tube to apply a deflecting force to bend the distal end region of the second guide tube , the second deflecting means adapted to bend the distal end region in a second articulated position the second guide tube lumen adapted for accommodating the first guide taught by Bolduc189 since combining two deflectable guide tubes allows for
the prosthesis being able to adapt to changes in the vessel morphology and able to be deployed and fastened safely and without damage to the native vessel, including a tortuous vessel.

As per claim 2, Bolduc189 and Bolduc389 teach a steerable guide catheter according to Claim 1, however, do not specifically disclose wherein the second articulated position is different than the first articulated position. It would have been obvious to one of ordinary skill in the art wherein the second articulated position is different than the first articulated position since second guide tube and first guide tube can be deflected independent of each other .

As per claim 3, Bolduc189 and Bolduc389 teach a steerable guide catheter according to Claim 1, however, do not specifically disclose wherein the second guide tube comprises a length that is shorter than the length of the first guide tube. It would have been obvious to one of ordinary skill in the art wherein the second guide tube comprises a length that is shorter than the length of the first guide since the deflectable second guide provide the access to the first articulated position while first guide can continue providing the access to the second articulated position as it exits from the distal end of the second guide.

As per claim 4, Bolduc189 further discloses an operative tool that applies one or more fasteners to tissue (abstract, para [0033]-[0037]).

----------See Supplemental Sheets----

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**

Continuation of:
Box V.2: Citations and Explanations:

As per claim 5, Bolduc189 teaches a steerable guide catheter comprising: a first guide tube having a length and defining an open interior lumen, the first guide tube lumen adapted for accommodating passage of an operative endovascular tool (abstract, para [0035], Fig. 15), a first handle assembly comprising a first deflecting means coupled to a distal end region of the first guide tube to apply a deflecting force to bend the distal end region of the first guide tube, the first deflecting means adapted to bend the distal end region in a first articulated position (para [0033]; Fig. 9. In one embodiment the control assembly 21 features a movable wheel or lever 22, which deflects the distal tip 23 of the directing device 18 to the desired location.), however, does not specifically disclose
a second guide tube having a length and defining an open interior lumen, the second guide tube lumen adapted for.accommodating passage of the first guide tube, and a second handle assembly comprising a second deflecting means coupled to a distal end region of the second guide tube to apply a deflecting force to bend the distal end region of the second. guide tube, the second deflecting means adapted to bend the distal end region in a second articulated position. Bolduc389 teaches wherein a system comprising a guide defining an access path into a vessel or hollow body organ and a fastener applier comprising a catheter sized and configured for introduction along the access path to a site targeted for implantation of at least one fastener (para [0008]) and wherein the distal portion of the guide tube 164 can be deflected in one direction and straightened by a steering wire coupled to a rotational deflector knob 170 on the handle 166 (para [0115]; Fig. 7A). It would have been obvious to one of ordinary skill in the art to use the teaching of Bolduc389 and utilize a second guide tube having a length and defining an open interior lumen, a second deflecting means coupled to a distal end region of the second guide tube to apply a deflecting force to bend the distal end region of the second guide tube , the second deflecting means adapted to bend the distal end region in a second articulated position the second guide tube lumen adapted for accommodating the first guide taught by Bolduc189 since combining two deflectable guide tubes allows for the prosthesis being able to adapt to changes in the vessel morphology and able to be deployed and fastened safely and without damage to the native vessel, including a tortuous vessel.

As per claim 6, Bolduc189 and Bolduc389 teach a steerable guide catheter according to Claim 5, however, do not specifically disclose wherein the second articulated position is different than the first articulated position. It would have been obvious to one of ordinary skill in the art wherein the second articulated position is different than the first articulated position since second guide tube and first guide tube can be deflected independent of each other.

As per claim 7, Bolduc189 and Bolduc389 teach a steerable guide catheter according to Claim 5, however, do not specifically disclose wherein the second guide tube comprises a length that is shorter than the length of the first guide tube. It would have been obvious to one of ordinary skill in the art wherein the second guide tube comprises a length that is shorter than the length of the first guide since the deflectable second guide provide the access to the first articulated position while first guide can continue providing the access to the second articulated position as it exits from the distal end of the second guide.

As per claim 8, Bolduc189 teaches a method comprising: providing a steerable guide catheter comprising: a first guide tube having a length and defining an open interior lumen, the first guide tube lumen adapted for accommodating passage of an operative endovascular tool (abstract, para [0035], Fig. 15), and a handle assembly comprising: a first deflecting means coupled to a distal end region of the first guide tube to apply a deflecting force to bend the distal end region of the first guide tube (para [0033]; Fig. 9; In one embodiment the control assembly 21 features a movable wheel or lever 22, which deflects the distal tip 23 of the directing device 18 to the desired location), passing the operative tool through the guide catheter, and operating the operative tool while residing in the guide catheter to apply at least one fastener to tissue (abstract, para [0035]; Fig. 15), however, does not specifically disclose a second guide tube having a length and defining an open interior lumen, the second guide tube lumen adapted for accommodating the first guide tube, and a second deflecting means coupled to a distal end region of the second guide tube to apply a deflecting force to bend the distal end region of the second guide tube, the second deflecting means adapted to bend the distal end region in a second articulated position. Bolduc389 teaches wherein a system comprising a guide defining an access path into a vessel or hollow body organ and a fastener applier comprising a catheter sized and configured for introduction along the access path to a site targeted for implantation of at least one fastener (para [0008]) and wherein the distal portion of the guide tube 164 can be deflected in one direction and straightened by a steering wire coupled to a rotational deflector knob 170 on the handle 166 (para [0115]; Fig. 7A.). It would have been obvious to one of ordinary skill in the art to use the teaching of Bolduc389 and utilize a second guide tube having a length and defining an open interior lumen, a second deflecting means coupled to a distal end region of the second guide tube to apply a deflecting force to bend the distal end region of the second guide tube , the second deflecting means adapted to bend the distal end region in a second articulated position the second guide tube lumen adapted for accommodating the first guide taught by Bolduc189 since combining two deflectable guide tubes allows for the prosthesis being able to adapt to changes in the vessel morphology and able to be deployed and fastened safely and without damage to the native vessel, including a tortuous vessel.

As per claim 9, Bolduc189 and Bolduc389 teach a method according to Claim 8: Bolduc189 further teaches including manipulating the first deflecting means for applying a deflecting force and bending the distal end region of the first guide tube in a first articulated position (para [0033]; Fig. 9.) however, does not specifically disclose manipulating the second deflecting means for applying a deflecting force and bending the distal end region of the second guide tube in a second articulated position. Bolduc389 teaches wherein the distal end of the steerable endovascular guide 30 can be deflected toward the first intended staple implantation area by rotating the deflector knob (para [0115]). It would have been obvious to one of ordinary skill in the art to use the teaching of Bolduc389 and manipulate the second deflecting means for applying a deflecting force and bending the distal end region of the second guide tube taught by Bolduc189 and Bolduc389 to allow for the prosthesis being able to adapt to changes in the vessel morphology and able to be deployed in a second articulated position.

----------See Supplemental Sheets-----

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**

Continuation of:
Supplemental Sheets: Box V.2: Citations and Explanations:

As per claim 10, Bolduc189 and Bolduc389 teach a method according to Claim 9, however, do not specifically disclose wherein the second articulated position is different than the first articulated position. It would have been obvious to one of ordinary skill in the art wherein the second articulated position is different than the first articulated position since second guide tube and first guide tube can be deflected independent of each other .

As per claim 11, Bolduc189 teaches a method comprising: providing a first guide tube having. a length and defining an, open interior lumen, the first guide tube lumen adapted for accommodating passage of an operative endovascular tool (abstract, para [0035]; Fig. 15), the first guide tube including a first handle assembly comprising a first deflecting means coupled to a distal end region of the first guide tube to apply a deflecting force to.bend the distal.end region of the first guide tube (para [0033], [0035]), passing the operative tool through the guide catheter, and operating the operative tool while residing in the guide catheter to apply at least one fastener to tissue (abstract, para [0035]. Fig. 15), however, does not specifically disclose providing a second guide tube having a length and defining an open interior lumen, the second guide tube lumen adapted for accommodating passage of the first guide tube, the second guide tube including a second handle assembly comprising a second deflecting means coupled to a distal end region of the second guide tube to apply a deflecting force to bend the distal end region of the second guide tube, inserting the first guide tube into the lumen of the second guide tube, advancing the first guide tube until the distal end region of the first guide tube extends beyond the distal end region of the second guide tube. Bolduc389 teaches wherein the distal end of the steerable endovascular guide 30 can be deflected toward the first intended staple implantation area by rotating the deflector knob on the handle (para [0115]; Fig. 7A.) and Bolduc389 teaches wherein a system comprising a guide defining an access path into a vessel or hollow body organ and a fastener applier comprising a catheter sized and configured for introduction along the access path to a site targeted for implantation of at least one fastener (para [0008]). It would have been obvious to one of ordinary skill in the art to use the teaching of Bolduc389 and utilize a second guide tube having a length and defining an open interior lumen, the second guide tube lumen adapted for accommodating passage of the first guide tube, the second guide tube including a second handle assembly comprising a second deflecting means coupled to a distal end region of the second guide tube to apply a deflecting force to bend the distal end region of the second guide tube and insert the first guide tube taught by Bolduc189 into the lumen of the second guide tube to advance the first guide tube until the distal end region of the first guide taught by into the lumen of the second guide tube, tube extends beyond the distal end region of the second guide tube to facilitate passage of the prosthesis through curved the vessel morphology.

As per claim 12, Bolduc189 and Bolduc389 teach a method according to Claim 11, and Bolduc189 teaches manipulating the first deflecting means for applying a deflecting force and bending the distal end region of the first guide tube in a first articulated position (para [0033]; Fig. 9.), however, does not specifically disclose manipulating the second deflecting means for applying a deflecting force and bending the distal end region of the second guide tube in a second articulated position. Bolduc389 teaches wherein the distal end of the steerable endovascular guide 30 can be deflected toward the first intended staple implantation area by rotating the deflector knob on the handle (para [0115]; Fig. 7A.). It would have been obvious to one of ordinary skill in the art to use the teaching of Bolduc389 and manipulate the second deflecting means for applying a deflecting force to the distal end of the tube in the method taught by Bolduc189 and Bolduc389 to bend the distal end region of the second guide tube in a second articulated position.

As per claim 13, Bolduc189 and Bolduc389 teach a method according to Claim 12, however, do not specifically disclose wherein the second articulated position is different than the first articulated position. It would have been obvious to one of ordinary skill in the art wherein the second articulated position is different than the first articulated position since second guide tube and first guide tube can be deflected independent of each other.

------See Supplemental Sheets---

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**

Continuation of:
Supplemental Sheets: Box V.2: Citations and Explanations:

As per claim 14, Bolduc189 teaches a steerable guide catheter system comprising: a first guide tube having a length and defining an open interior lumen, the first guide tube lumen adapted for accommodating passage of an operative endovascular tool (abstract, para [0035]; Fig. 15), and a handle assembly comprising: a first deflecting means coupled to a distal end region of the first guide tube to apply a deflecting force to bend the distal end region of the first guide tube, the first deflecting means adapted to bend the distal end region in a first articulated position (para [0033]), however, does not specifically disclose a second guide tube having a length and defining an open interior lumen, the second guide tube lumen adapted for accommodating the first guide tube, a second deflecting means coupled to a distal end region of the second guide tube to apply a deflecting force to bend the distal end region of the second guide tube, the second deflecting means adapted to bend the distal end region in a second articulated position, and instructions for use describing the use of the steerable guide catheter system, the instructions comprising the operations of introducing into a vessel the steerable guide catheter, advancing the steerable guide catheter to the targeted site in the vessel, manipulating the first deflecting means for applying a deflecting force and bending the distal end region of the first guide .tube in a first articulated position, and manipulating the second deflecting means for applying a deflecting force and bending the distal end region of the second guide tube in a second articulated position. Bolduc389 teaches wherein a system comprising a guide defining an access path into a vessel or hollow body organ and a fastener applier comprising a catheter sized and configured for introduction along the access path to a site targeted for implantation of at least one fastener (para [0008]) and wherein the distal portion of the guide tube 164 can be deflected in one direction and straightened by a steering wire coupled to a rotational deflector knob 170 on the handle 166 (para [0115]; Fig. 7A.), and wherein the instructions for use 58 can be embodied in separate instruction manuals, or in video or audio recordings or provided in an internet web page (para [0054]) and wherein The instructions for use 58 can direct use of catheter-based technology via a peripheral intravascular access site, such as in the femoral artery, optionally with the assistance of image guidance (para [0161]). It would have been obvious to one of ordinary skill in the art to use the teaching of Bolduc389 and utilize a second guide tube having a length and defining an open interior lumen, the second guide tube lumen adapted for accommodating the first guide tube, a second deflecting means coupled to a distal end region of the second guide tube to apply a deflecting force to bend the distal end region of the second guide tube, the second deflecting means adapted to bend the distal end region in a second articulated position in the method taught by Bolduc189 since combining two deflectable guide tubes allows for the prosthesis being able to adapt to changes in the vessel morphology and able to be deployed and fastened safely and without damage to the native vessel, including a tortuous vessel. It would have been obvious to one of ordinary skill in the art to use the teaching of Bolduc389 and utilize instructions for use describing the use of. the steerable guide catheter system, the instructions comprising the operations of introducing into a vessel the steerable guide catheter, advancing the steerable guide catheter to the targeted site in the vessel, manipulating the first deflecting means for applying a deflecting force and bending the distal end region of the first guide tube in a first articulated position, and manipulating the second deflecting means for applying a deflecting force and bending the distal end region of the second guide tube in a second articulated position in the system taught by Bolduc189 to facilitate that procedure is performed quickly and accurately.

As per claim 15, Bolduc189 and Bolduc389 teach a system according to Claim 14, however, do not specifically disclose wherein the second articulated position is different than the first articulated position. It would have been obvious to one of ordinary skill in the art wherein the second articulated position is different than the first articulated position since second guide tube and first guide tube can be deflected independent of each other

As per claim 16, Bolduc189 further discloses further including the operative tool, the operative tool adapted to apply at least one fastener to tissue while residing in the guide catheter (abstract, para [0033]-[0037].Fig. 15.).

As per claim 17, Bolduc189 further discloses wherein the instructions for use further include instructions comprising passing the operative tool 35 through the guide catheter, and operating the operative tool while residing in the guide catheter to apply at least one fastener to tissue (para [0035]. Fig. 15.).

As per claim 18, Bolduc189 teaches a steerable guide catheter comprising: a first guide tube having a length and defining an open interior lumen, the first guide tube lumen adapted for accommodating passage of an operative endovascular tool (abstract, para [0035]), and a handle assembly comprising: a first deflecting means coupled to a distal end region of the first guide tube to apply a deflecting force to bend the distal end region of the first guide tube, the first deflecting means adapted to bend the distal end region in a first articulated position (para [0033]), however, does not specifically disclose wherein a second deflecting means coupled to the distal end region of the first' guide tube to apply a deflecting force to bend the distal end region of the first guide tube, the second deflecting means adapted to bend the distal end region in a second articulated position. Bolduc389 teaches wherein the distal portion of the guide tube 164 can be deflected in one direction and straightened by a steering wire coupled to a rotational deflector knob 170 on the handle 166 (para [0115];Fig. 7A). It would have been obvious to one of ordinary skill in the art to use the teaching of Bolduc389 and utilize a second deflecting means (deflector knob) coupled to the distal end region of the first guide tube, the second deflecting means adapted to apply a deflecting force to bend the distal end region of the first guide tube in the steerable catheter guide taught by Bolduc189 to bend the distal end region in a second articulated position.

As per claim 19, Bolduc189 and Bolduc389 teach a steerable guide catheter according to Claim 18, however, do not specifically disclose wherein the second articulated position is different than the first articulated position. It would have been obvious to one of ordinary skill in the art wherein the second articulated position is different than the first articulated position since second guide tube and first guide tube can be deflected independent of each other.

-----See Supplemental Sheets---

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**

Continuation of:
Supplemental Sheets: Box V.2: Citations and Explanations:

As per claim 20, Bolduc189 further discloses an operative tool that applies one or more fasteners to tissue (abstract).

As per claim 21, Bolduc189 and Bolduc389 teach a steerable guide catheter according to Claim 18, however, do not specifically disclose a second guide tube having a length and defining an open interior lumen, the second guide tube lumen adapted for accommodating the first guide tube, and the second deflecting means coupled to the distal end region of the second guide tube to apply a deflecting force to bend the distal end region of the second guide tube, the second deflecting means adapted to bend the distal end region in the second articulated position. Bolduc389 teaches wherein the distal portion of the guide tube 164 can be deflected in one direction and straightened by a steering wire coupled to a rotational deflector knob 170 on the handle 166 (para [0115]; Fig. 7A). It would have been obvious to one of ordinary skill in the art to use the teaching of Bolduc389 and utilize a second guide tube having a length and defining an open interior lumen, the second guide tube lumen adapted for accommodating the first guide tube, and the second deflecting means coupled to the distal end region of the second guide tube to apply a deflecting force to bend the distal end region of the second guide tube, the second deflecting means adapted in the system taught by Bolduc189 to bend the distal end region in the second articulated position and facilitate passage of the prosthesis through curved vessel morphology.

As per claim 22, Bolduc189 and Bolduc389 teach a steerable guide catheter according to Claim 21, however, do not specifically disclose wherein the second guide tube comprises a length that is shorter than the length of the first guide tube. It would have been obvious to one of ordinary skill in the art wherein the second guide tube comprises a length that is shorter than the length of the first guide since the deflectable second guide provide the access to the first articulated position while first guide can continue providing the access to the second articulated position as it exits from the distal end of the second guide.

Claims 1-22 have industrial applicability as defined by PCT Article 33 (4) because the subject matter can be made or used by the industry.

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To:
RYAN KROMHOLZ & MANION, S.C.
P.O. BOX 26618
MILWAUKEE, WI 53226-0618

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

	Date of mailing *(day/month/year)* 18 DEC 2009
Applicant's or agent's file reference 20397-A PCT	**FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/US 09/05609	International filing date *(day/month/year)* 14 October 2009 (14.10.2009)
Applicant APTUS ENDOSYSTEMS, INC.	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

   Filing of amendments and statement under Article 19:
   The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

   When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

   Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes 1211 Geneva 20, Switzerland, Facsimile No.: +41 22 338 8270

   For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

   ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

   ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

   Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90*bis*.1 and 90*bis*.3, respectively, before the completion of the technical preparations for international publication.

   The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

   Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

   In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

   See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 20397-A PCT	**FOR FURTHER ACTION**	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/US 09/05609	International filing date *(day/month/year)* 14 October 2009 (14.10.2009)	(Earliest) Priority Date *(day/month/year)* 16 October 2008 (16.10.2008)
Applicant APTUS ENDOSYSTEMS, INC.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 2 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

a. With regard to the **language**, the international search was carried out on the basis of:

☒ the international application in the language in which it was filed.

☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).

c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (see Box No. II).

3. ☐ **Unity of invention is lacking** (see Box No. III).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

a. the figure of the **drawings** to be published with the abstract is Figure No. 13A

☐ as suggested by the applicant.

☒ as selected by this Authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

b. ☐ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 09/05609

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61F 2/06 (2009.01)
USPC - 623/1.23; 600/585
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC - A61F 2/06 (2009.01)
USPC - 623/1.23; 600/585

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC - 600/434, 466

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PubWEST (DB=PGPB,USPT,USOC,EPAB,JPAB), Google Scholar

Search Terms - graft, stent, staple, vessel wall, catheter, fastener, prosthesis, steerable, guide, staple

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 2007/0073389 A1 (BOLDUC ET AL.) 29 March 2007 (29.03.2007) entire document	1, 3-7, 13-20 --- 2, 8-12, 21-22
Y	US 2008/0065189 A1 (BOLDUC) 13 March 2008 (13.03.2008) entire document, especially para [0033]; Fig 11	2, 11-12, 21-22
Y	US 2008/0097489 A1 (GOLDFARB ET AL.) 24 April 2008 (24.04.2008) entire document, especially para [0227], [0232]; Fig 61B	8-10

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
04 December 2009 (04.12.2009)	18 DEC 2009
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: RYAN KROMHOLZ & MANION, S.C.
P.O. BOX 26618
MILWAUKEE, WI 53226-0618

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	18 DEC 2009
Applicant's or agent's file reference 20397-A PCT	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US 09/05609	14 October 2009 (14.10.2009)	16 October 2008 (16.10.2008)

International Patent Classification (IPC) or both national classification and IPC
IPC(8) - A61F 2/06 (2009.01)
USPC - 623/1.23; 600/585

Applicant APTUS ENDOSYSTEMS, INC.

1. This opinion contains indications relating to the following items:

- [X] Box No. I Basis of the opinion
- [ ] Box No. II Priority
- [ ] Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- [ ] Box No. IV Lack of unity of invention
- [X] Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- [ ] Box No. VI Certain documents cited
- [ ] Box No. VII Certain defects in the international application
- [ ] Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US	Date of completion of this opinion	Authorized officer:
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	04 December 2009 (04.12.2009)	Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 09/05609

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed.

   ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing filed or furnished:

   a. (means)

      ☐ on paper

      ☐ in electronic form

   b. (time)

      ☐ in the international application as filed

      ☐ together with the international application in electronic form

      ☐ subsequently to this Authority for the purposes of search

4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 09/05609

Box No. V **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	2, 8-12, 21-22	YES
	Claims	1, 3-7, 13-20	NO
Inventive step (IS)	Claims	NONE	YES
	Claims	1-22	NO
Industrial applicability (IA)	Claims	1-22	YES
	Claims	NONE	NO

2. Citations and explanations:

Claims 1, 3-7, and 13-20 lack novelty under PCT Article 33(2) as being anticipated by US 2007/0073389 A1 by Bolduc et al. (hereinafter "Bolduc '389").

Regarding claim 1, Bolduc '389 discloses a system for modifying a prosthesis to conform to a vessel wall comprising:

a catheter system sized and configured for introduction to a targeted site in the vessel (para [0113]-[0115]; Fig 7A-B, element 164),

the catheter system adapted to apply a resolution of force to the prosthesis to modify the shape of the prosthesis to conform the shape of the prosthesis to the shape of the vessel wall (para [0184]), and

the catheter system adapted to position a fastener in at least one region of the prosthesis to maintain the conformed shape of the prosthesis to the vessel wall (para [0173], [0187]).

Regarding claim 3, Bolduc '389 discloses claim 1. Bolduc further discloses the catheter system further including a lumen for passage of an endovascular device to the targeted site in the vessel (para [0126]; Fig 11A, element 168).

Regarding claim 4, Bolduc '389 discloses claim 3. Bolduc further discloses a fastening device sized and configured for introduction through the catheter system lumen to the targeted site in the vessel (para [0126]; Fig 9A, element 38).

Regarding claim 5, Bolduc '389 discloses claim 4. Bolduc further discloses the fastening device including an actuator to deploy the fastener in at least one region of the prosthesis to maintain the conformed shape of the prosthesis to the vessel wall (para [0126], [0127]; Fig 9B, element 192).

Regarding claim 6, Bolduc '389 discloses claim 1. Bolduc further discloses the catheter system comprising a steerable guide device (para [0114]).

Regarding claim 7, Bolduc '389 discloses claim 6. Bolduc further discloses the steerable guide device comprising a distal portion adapted to deflect in at least a first position (para [0115]; Fig 7A).

Regarding claim 13, Bolduc '389 discloses a system for modifying a prosthesis to conform to a vessel wall comprising:

a steerable guide device sized and configured for introduction to a targeted site in the vessel, the steerable guide device including a lumen for passage of an endovascular device to the targeted site in the vessel (para [0115]; Fig 7A, element 30, 168),

a fastening device sized and configured for introduction through the steerable guide device lumen to the targeted site in the vessel (para [0126]-[0127]; Fig 9A-B element 38), the steerable guide device adapted to apply a resolution of force to the prosthesis to modify the shape of the prosthesis to conform the shape of the prosthesis to the vessel wall (para [0183]), and the fastening device including an actuator (para [0126], [0127]; Fig 9B, element 192) to deploy a fastener in at least one region of the prosthesis to maintain the conformed shape of the prosthesis to the vessel wall (para [0187]).

---Continued in Supplemental Box---

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:
---Box V, Section 2---

Regarding claim 14, Bolduc '389 discloses a method of modifying a prosthesis to conform to a vessel wall comprising:

providing a steerable guide device sized and configured for introduction to a targeted site in the vessel , the steerable guide device including a lumen for passage of an endovascular device to the targeted site in the vessel (para [0115]; Fig 7A, element 30, 168),

providing a staple applier sized and configured for introduction through the steerable guide device lumen to the targeted site in the vessel (para [0126]-[0127]; Fig 9A-B element 38), the staple applier including an actuator for deploying a staple in at least one region of the prosthesis for maintaining the shape of the prosthesis to the vessel wall (para [0126], [0127]; Fig 9B, element 192),

introducing into the vessel the steerable guide device (para [0176]),

advancing the steerable guide device to the targeted site in the vessel (para [0176]),

positioning a distal end of the steerable guide device against the prosthesis (para [0183]-[0184]),

positioning a distal portion of the steerable guide device against the prosthesis or vessel wall away from the distal end (para [0183]-[0184]),

advancing the staple applier through the steerable guide device lumen until the staple applier emerges from the distal end of the steerable guide device and contacts the prosthesis (para [0183]-[0184]),

continuing to advance the staple applier until the staple applier is applying a resolution of force to the prosthesis and modifying the shape of the prosthesis and conforming the shape of the prosthesis to the vessel wall (para [0184}, and

deploying a staple in at least one region of the prosthesis, the staple maintaining the conforming shape of the prosthesis to the vessel wall (para [0185]).

Regarding claim 15, Bolduc '389 discloses a method of modifying a prosthesis comprising:

providing a prosthesis adapted for endovascular delivery and implantation, the prosthesis including a delivery shape and a deployed shape (para [0084]),

delivering the prosthesis to a target site (para [0165]),

deploying the prosthesis at the target site causing the prosthesis to change shape from the delivery shape to the deployed shape (para [0082] - releasing release wires S1, S2, and S3 cause a change in shape from the delivery shape to the deployed shape), and

manipulating the prosthesis by implanting a fastener through the prosthesis causing the prosthesis to change shape from the deployed shape to an implanted shape different from the deployed shape (para [0184]).

Regarding claim 16, Bolduc '389 discloses claim 15. Bolduc further discloses the fastener being implanted through the prosthesis and into tissue (para [0185]).

Regarding claim 17, Bolduc '389 discloses claim 15. Bolduc further discloses the implanted shape conforming to a shape of the target site (para [0184]).

Regarding claim 18, Bolduc '389 discloses claim 17. Bolduc further discloses the target site comprising a tortuous vessel (para [0045] - aortic arch is a tortuous vessel).

Regarding claim 19, Bolduc '389 discloses claim 15. Bolduc '389 further discloses the prosthesis further including a proximal portion and a distal portion, and manipulating the prosthesis including manipulating the proximal portion of the prosthesis by implanting a fastener through the proximal portion of the prosthesis causing the proximal portion of the prosthesis to change shape from the deployed shape to an implanted shape different from the deployed shape (para [0184]; Fig 10C - fastener changes the shape of the prosthesis to make it conform to the shape of the vessel wall).

Regarding claim 20, Bolduc discloses claim 19. Bolduc '389 further discloses the prosthesis distal portion maintaining its deployed shape and being not manipulated to change shape from its deployed shape to an implanted shape (para [0217]-[0218] - distal portion is not manipulated; it expands to its implanted shape).

---Continued in Supplemental Box---

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 09/05609

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:
---Box V, Section 2---

Claims 2, 11-12, and 21-22 lack an inventive step under PCT Article 33(3) as being obvious over Bolduc '389 in view of US 2008/0065189 A1 ("Bolduc '189").

Regarding claim 2, Bolduc '389 discloses claim 1. Bolduc '389 discloses the catheter system being adapted to push against the prosthesis and against the vessel wall at the desired fastener position (para [0187]), but does not disclose the catheter system being adapted to push against the generally opposite vessel wall for application of the resolution of force for fastener position. Bolduc '189 discloses a similar catheter system being adapted to push against the generally opposite vessel wall for application of the resolution force for fastener position (para [0033]; Fig 11, element 24 - strut assembly 24 is adapted to push against vessel wall, as depicted in Fig 11). It would have been obvious to one of ordinary skill in the art to combine the catheter system disclosed by Bolduc with the catheter system being adapted to push against the generally opposite vessel wall for application of the resolution of force for fastener position, as such a adaptation increases the force the clinician may use when placing a fastener.

Regarding claim 11, Bolduc '389 discloses method of modifying a prosthesis to conform to a vessel wall comprising:

providing a catheter system sized and configured for introduction to a targeted site in the vessel (para [0176]),

introducing into the vessel the catheter system (para [0176),

advancing the catheter system to the targeted site in the vessel (para [0176]),

positioning a distal end of the catheter system against the prosthesis (para [0183]-[0184]),

continuing to advance the catheter system until the catheter system is applying a resolution of force to the prosthesis and modifying the shape of the prosthesis and conforming the shape of the prosthesis to the vessel wall (para [0183]-[0184]), and

deploying a staple in at least one region of the prosthesis, the staple maintaining the conforming shape of the prosthesis to the vessel wall (para [0187]).

Bolduc '389 does not disclose the step of positioning a distal portion of the catheter system against the prosthesis or vessel wall away from the distal end. Bolduc '189 discloses the step of positioning distal portion of the catheter system against the prosthesis or vessel wall away from the distal end (para [0033]; Fig 11, element 24 - strut assembly 24 is adapted to push against vessel wall, as depicted in Fig 11, away from the distal end). It would have been obvious to one of ordinary skill in the art to perform the step disclosed by Bolduc '189 as such a step increases the force the clinician may use when placing a fastener.

Regarding claim 12, Bolduc '389 and Bolduc '189 disclose claim 11. Bolduc further discloses providing a staple applier sized and configured for introduction through a catheter system lumen to the targeted site in the vessel, the staple applier including an actuator for deploying the staple in at least one region of the prosthesis for maintaining the shape of the prosthesis to the vessel wall (para [0184]-[0185]).

Regarding claim 21, Bolduc '389 discloses a catheter system comprising:

a catheter system sized and configured for introduction to a targeted site in the vessel (para [0113] - [0115]; Fig 7A-B, element 164),

the catheter system adapted to apply a resolution of force to a prosthesis to modify the shape of the prosthesis to conform the shape of the prosthesis to the shape of the vessel wall (para [0184]),
the catheter system adapted to position a fastener in at least one region of the prosthesis to maintain the conformed shape of the prosthesis to the vessel wall (para [0187]), and
instructions for use describing the use of the catheter system (para [0165]; Fig 2, element 58), the instructions comprising the operations of
introducing into the vessel the catheter system (para [0176),
advancing the catheter system to the targeted site in the vessel (para [0176]),
positioning a distal end of the catheter system against the prosthesis (para [0183]-[0184]),
positioning a distal portion of the catheter system against the prosthesis or vessel wall away from the distal end,
continuing to advance the catheter system until the catheter system is applying a resolution of force to the prosthesis and modifying the shape of the prosthesis and conforming the shape of the prosthesis to the vessel wall, and deploying a staple in at least one region of the prosthesis, the staple maintaining the conforming shape of the prosthesis to the vessel wall.continuing to advance the catheter system until the catheter system is applying a resolution of force to the prosthesis and modifying the shape of the prosthesis and conforming the shape of the prosthesis to the vessel wall (para [0183]-[0184]), and

deploying a staple in at least one region of the prosthesis, the staple maintaining the conforming shape of the prosthesis to the vessel wall (para [0187]).

Bolduc '389 does not disclose the step of positioning a distal portion of the catheter system against the prosthesis or vessel wall away from the distal end. Bolduc '189 discloses the step of positioning distal portion of the catheter system against the prosthesis or vessel wall away from the distal end (para [0033]; Fig 11, element 24 - strut assembly 24 is adapted to push against vessel wall, as depicted in Fig 11, away from the distal end). It would have been obvious to one of ordinary skill in the art to perform the step disclosed by Bolduc '189 as such a step increases the force the clinician may use when placing a fastener.

---Continued in Supplemental Box---

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:
---Section V, Section 2---

Regarding claim 22, Bolduc '389 and Bolduc '189 disclose claim 21.Bolduc '189 further discloses the catheter system being adapted to push against the prosthesis and against the vessel wall at the desired fastener position, and the catheter system is adapted to push against the generally opposite vessel wall for application of the resolution of force for fastener position (para [0033]; Fig 11, element 24 - strut assembly 24 is adapted to push against vessel wall, as depicted in Fig 11).

Claims 8-10 lack an inventive step under PCT Article 33(3) as being obvious over Bolduc '389 in view of US 2008/0097489 A1 by Goldfarb et al. (hereinafter "Goldfarb").

Regarding claim 8, Bolduc disclose claim 6. Bolduc '389 does not disclose the steerable guide device comprising a distal portion adapted to deflect in at least a first position and a second position. Goldfarb discloses a steerable guide device comprising a distal portion adapted to deflect in at least a first position and a second position (para [0227], [0232]; Fig 61B). It would have been obvious to one of ordinary skill in the art to combine the catheter system disclosed by Boldus with the distal portion adapted to deflect in at least a first and second direction and a two-axis deflection catheter would be better able to navigate tortuous the pathways of the cardiovascular system.

Regarding claim 9, Bolduc '389 and Goldfarb disclose claim 8. Goldfarb further discloses the second position being different than the first position (para [0227], [0232]; Fig 61B).

Regarding claim 10, Bolduc '389 and Goldfarb disclose claim 8. Goldfarb further discloses the steerable guide device comprising a first steerable guide and a second steerable guide (para [0227]; Fig 61B, elements 1000, 1020).

Claims 1-22 have industrial applicability as defined by PCT Article 33(4) as the subject matter can be made or used in industry.

PTO/SB/05 (08-08)
Approved for use through 09/30/2010. OMB 0651-0032
U.S. Patent and Trademark Office. U.S. DEPARTMENT OF COMMERCE

UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.	9494.19047-C DIV
First Inventor	Bolduc
Title	
Express Mail Label No.	

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

1. ☐ **Fee Transmittal Form** (e.g., PTO/SB/17)
2. ☑ **Applicant claims small entity status.** See 37 CFR 1.27.
3. ☑ **Specification** [*Total Pages* 72]
   Both the claims and abstract must start on a new page
   (For information on the preferred arrangement, see MPEP 608.01(a))
4. ☑ **Drawing(s)** (*35 U.S.C. 113*) [*Total Sheets* 44]
5. **Oath or Declaration** [*Total Sheets* _____]
   a. ☐ Newly executed (original or copy)
   b. ☐ A copy from a prior application (37 CFR 1.63(d))
   (for continuation/divisional with Box 18 completed)
   i. ☐ DELETION OF INVENTOR(S)
   Signed statement attached deleting inventor(s) name in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).
6. ☑ **Application Data Sheet.** See 37 CFR 1.76
7. ☐ **CD-ROM or CD-R** in duplicate, large table or Computer Program *(Appendix)*
   ☐ Landscape Table on CD
8. **Nucleotide and/or Amino Acid Sequence Submission**
   (if applicable, items a. – c. are required)
   a. ☐ Computer Readable Form (CRF)
   b. Specification Sequence Listing on:
      i. ☐ CD-ROM or CD-R (2 copies); or
      ii. ☐ Paper
   c. ☐ Statements verifying identity of above copies

ADDRESS TO: **Commissioner for Patents**
P.O. Box 1450
Alexandria VA 22313-1450

ACCOMPANYING APPLICATION PARTS

9. ☐ **Assignment Papers** (cover sheet & document(s))
   Name of Assignee_____
10. ☐ **37 CFR 3.73(b) Statement** *(when there is an assignee)* ☐ **Power of Attorney**
11. ☐ **English Translation Document** *(if applicable)*
12. ☐ **Information Disclosure Statement** (PTO/SB/08 or PTO-1449)
    ☐ Copies of citations attached
13. ☐ **Preliminary Amendment**
14. ☐ **Return Receipt Postcard** (MPEP 503)
    (Should be specifically itemized)
15. ☐ **Certified Copy of Priority Document(s)**
    (if foreign priority is claimed)
16. ☐ **Nonpublication Request** under 35 U.S.C. 122(b)(2)(B)(i). Applicant must attach form PTO/SB/35 or equivalent.
17. ☐ Other:_____

18. If a CONTINUING APPLICATION, *check appropriate box, and supply the requisite information below and in the first sentence of the specification following the title, or in an Application Data Sheet under 37 CFR 1.76:*

☐ Continuation ☑ Divisional ☐ Continuation-in-part (CIP) of prior application No.: 11/254,950

Prior application information: *Examiner* John C. Hong *Art Unit:* 3726

19. CORRESPONDENCE ADDRESS

☑ The address associated with Customer Number: 26308 *OR* ☐ Correspondence address below

Name					
Address					
City		State		Zip Code	
Country		Telephone		Email	

Signature		Date	11/2/2010
Name (Print/Type)	Patrick J. Fleis	Registration No. (Attorney/Agent)	55,185

PTO/SB/14 (11-08)
Approved for use through 09/30/2010. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	9494.19047-C DIV
	Application Number	
Title of Invention	Devices, Systems, and Methods for Prosthesis Delivery and Implantation, Including the Use of a Fastener Tool	

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

Secrecy Order 37 CFR 5.2

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Applicant Information:

Applicant 1

Applicant Authority ◉ Inventor ○ Legal Representative under 35 U.S.C. 117 ○ Party of Interest under 35 U.S.C. 118

Prefix	Given Name	Middle Name	Family Name	Suffix
	Lee		Bolduc	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Sunnyvale	State/Province	CA	Country of Residence	US

Citizenship under 37 CFR 1.41(b) US

Mailing Address of Applicant:

Address 1	716 Grape Avenue		
Address 2			
City	Sunnyvale	State/Province	CA
Postal Code	94087	Country	US

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below.
For further information see 37 CFR 1.33(a).

☐ **An Address is being provided for the correspondence Information of this application.**

Customer Number	26308		
Email Address	rkmippatent@rkmiplaw.com	Add Email	Remove Email

Application Information:

Title of the Invention	Devices, Systems, and Methods for Prosthesis Delivery and Implantation, Including the Use of a Fastener Tool		
Attorney Docket Number	9494.19047-C DIV	Small Entity Status Claimed	☒
Application Type	Nonprovisional		
Subject Matter	Utility		
Suggested Class (if any)		Sub Class (if any)	
Suggested Technology Center (if any)			
Total Number of Drawing Sheets (if any)	44	Suggested Figure for Publication (if any)	

PTO/SB/14 (11-08)
Approved for use through 09/30/2010. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	9494.19047-C DIV
	Application Number	
Title of Invention	Devices, Systems, and Methods for Prosthesis Delivery and Implantation, Including the Use of a Fastener Tool	

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)
☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S. C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32). Enter either Customer Number or complete the Representative Name section below. If both sections are completed the Customer Number will be used for the Representative Information during processing.

Please Select One:	◉ Customer Number	○ US Patent Practitioner	○ Limited Recognition (37 CFR 11.9)
Customer Number	26308		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, or 365(c) or indicate National Stage entry from a PCT application. Providing this information in the application data sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78(a)(2) or CFR 1.78(a)(4), and need not otherwise be made part of the specification.

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
	Division of	11254950	2005-10-20

Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button.

Foreign Priority Information:

This section allows for the applicant to claim benefit of foreign priority and to identify any prior foreign application for which priority is not claimed. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55(a).

Remove

Application Number	Country	Parent Filing Date (YYYY-MM-DD)	Priority Claimed
			○ Yes ◉ No

Additional Foreign Priority Data may be generated within this form by selecting the **Add** button.

Assignee Information:

Providing this information in the application data sheet does not substitute for compliance with any requirement of part 3 of Title 37 of the CFR to have an assignment recorded in the Office.

Assignee 1

PTO/SB/14 (11-08)
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Title of Invention	Devices, Systems, and Methods for Prosthesis Delivery and Implantation, Including the Use of a Fastener Tool	

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DEVICES, SYSTEMS, AND METHODS FOR PROSTHESIS DELIVERY AND IMPLANTATION, INCLUDING THE USE OF A FASTENER TOOL

Related Applications

This application is divisional of c o-pending United States Patent Application Serial No. 11/254,950, filed 20 October 2005, which is a continuati on-in-part of c o-pending United Stated Patent Application Serial No. 11/254,619, filed 20 October 2005, and entitled "Devices, Systems, and Methods for Guiding an Operative Tool Into an Interior Body Reg ion", which is i ncorporated herei n by reference. United States Pat ent Application S erial No. 11/254, 950 also is a continuation-in-part of United Sta ted Patent Applic ation Serial No. 10/692,283, filed 23 October 2003, now U.S. Patent No. 7,147,657, and entitled "Prosthesis Delivery System s and Methods," which claims the benefit of United States Provisional Patent Application Serial No . 60/488,753, filed 21 July 2003, and entitled "Endoprosthesis Delivery Systems and Methods." United States Patent Application Serial No. 11/254,950 also is a continuation-in-part of co -pending United Stated Patent Application Serial No. 10/78 6,465, filed 25 F ebruary 2004, and entitled "Systems and Methods for Attaching a Prosthesis Within a Body Lumen or Hollow O rgan," which is a continuation-in-part of co -pending United States Patent Application 10/693,255, now U.S. Patent No . 6,929,661, and entitled "Multi -Lumen Prosthesis Systems and Methods," which claims the benefit of United States Provisional Patent Application Serial No. 60/489,011, filed July 21, 20 03, and entitled "Bifurcated Prosthesis Systems and Methods." Unit ed States Patent Application Serial No. 11/254,950 also is a continuation -in-part of co-pending United Stated Patent A pplication Serial No. 10/307,226 , filed 29 November 2002, and entitled "I ntraluminal Prosthesis Attachment Systems and Methods." United States P atent Application Serial No. 11/254,950 is also a continuation -in-part of U.S. Patent Application Serial No. 10/669,881, filed 24 September 2003, now U.S. Patent No. 7,491, 232, entitle d "Ca theter-Based Fastener Implantation Apparatus and Methods with Implantation Force Resolutions." United States Patent A pplication Serial No. 11/254,95 0 is also a continuation-in-part of U.S. Patent Application Serial No. 11/166,411,

filed 24 June 2005, entitled "Endovascular Aneurysm Repair System," which is a division of U.S. Patent Application Serial No. 10/271,334, filed 15 October 2002, now U.S. Patent No. 6,960,217, which claims the benefit of U.S. Provisional Patent Application Serial No. 60/333,937, filed 28 November 2001, and entitled "Endovascular Aneurysm Repair System."

Field of the Invention

The invention relates generally to devices, systems, and methods for the delivery and implantation of a prosthesis to a targeted site within the body, e.g., for the repair of diseased and/or damaged sections of a hollow body organ and/or blood vessel.

Background of the Invention

The weakening of a vessel wall from damage or disease can lead to vessel dilatation and the formation of an aneurysm. Left untreated, an aneurysm can grow in size and may eventually rupture.

For example, aneurysms of the aorta primarily occur in the abdominal region, usually in the infrarenal area between the renal arteries and the aortic bifurcation. Aneurysms can also occur in the thoracic region between the aortic arch and renal arteries. The rupture of an aortic aneurysm results in massive hemorrhaging and has a high rate of mortality.

Open surgical replacement of a diseased or damaged section of vessel can eliminate the risk of vessel rupture. In this procedure, the diseased or damaged section of vessel is removed and a prosthetic prosthesis, made either in a straight or bifurcated configuration, is installed and then permanently attached and sealed to the ends of the native vessel by suture. The prosthetic prosthesis for these procedures are usually unsupported woven tubes and are typically made from polyester, ePTFE or other suitable materials. The prosthesis are longitudinally unsupported so they can accommodate changes in the morphology of the aneurysm and native vessel. However, these procedures require a large surgical incision and have a high rate of morbidity and mortality. In addition, many patients are unsuitable for this type of major surgery due to other co-morbidities.

Endovascular aneurysm repair has been introduced to

overcome the pro blems associated with open surg ical repair. The aneurysm is brid ged with a vascular prosthesis, which is place d intraluminally. Typically these p rosthetic prostheses for aortic aneurysms are delivered collapsed on a catheter through the femoral artery. These prostheses are usually designed with a fabric material attached to a meta llic scaffolding (stent) structure, which expands or is expanded to contact the internal diameter of the vessel. Unlike open surgical aneurysm repair, intraluminally deployed prostheses are not sutured to th e native vessel, but rely on eithe r barbs extendin g from the stent, which penetrate into the nativ e vessel during deployment, or the radial expansion forc e of the stent itself is utilized to hold the prosthesis in position. These prosthesis attachment means do not provide t he same level of attachment when compared to suture and can damage the native vessel upon deployment.

Accordingly, there is a need fo r improved prosthesis delivery devices, systems, and methods that deliver a prosthetic graft to a body lumen, the prosthesis being able to adapt to changes in aneurysm morphology and able to be deployed safely and without damage to the native vessel.

Summary of the Invention

The devices, systems, and methods for delivering and implanting radial ly expandable pr ostheses in the body lumens are described. In pa rticular, the pr esent invention provides improved devices, systems, and methods for implanting vascular prostheses into blood vessels, including both arterial and venous systems. In the exemplary embodiments, prostheses are placed in vasculature to reinforce aneurysms, particularly abdominal aortic aneurysms.

One aspect of the invention provides devices, s ystems, and methods for fasten ing a prosthesis into a hollow bod y organ or bloo d vessel. The devices, systems, and methods include a fastener applier that is sized and configured for securing a prosthesis, the fastener applier comprising a handle assembly positioned at the caudal end of the fastener applier, a fastener applier shaft coupled to the handle assembly, and a fastener driver f or advancing a f astener into the prosthesis and tissue, the fastener driver coupled to the fastener

applier shaft at the cephalad end of the fastener a pplier shaft, th e fastener driver including a housing and a release latch, wherein the release latch prevents premature release of the fastener from the fastener driver. The fastener driv er housing may a lso include an internally thread ed portion and a non -threaded po rtion, the non - threaded portion providing an area where the fastener can be rotated but not advanced o ut of the driver, the advancement o ut of the driver only taking place if the fastener has been previously engaged in tissue or the prosthesis.

In one embodiment, the handle assem bly may further i nclude a motion control assembly to be used by an ope rator, the motion control assembly providing motion control of the fa stener within the fastener driver. The motion contr ol assembly may include a forward control function and a reverse con trol function. The handle assembly may also include an indication assembly to provide information to an operator, the indication assembly providing at least one of an audible and visual in dication. The information provided may include at leas t one of a fastene r position or ti ming or status o r error, or any combination.

In one embodiment , fastener is a helical fastener . The helical fastener m ay include a fast ener body having a distal end fo r penetrating tissue in response to a force and a proximal end fo r releasably coupling the fastener body to the fastener applier, and a stop structure as sociated with the proximal end to prevent over - penetration of th e fastener body into tissue, the stop s tructure bisecting the diameter of the fastener body. The stop structure may be offset from the diameter of the fastener body.

An additional asp ect of the inven tion provides dev ices, systems, and meth ods for storing a fastener used for securing a prosthesis into a hollow body orga n or blood vessel . The devices , systems, and methods comprise a base structure, and at least one receptacle positioned within the base structure, the receptacle sized and configured t o releasably sto re at least one fastener. The receptacle may be sized and co nfigured to releasabl y store at le ast one helical fastener. The helical fastener may include a fastener body

having a distal end for penetrating tissue in response to a force and a proximal end for releasably coupling the fastener body to the fastener applier, and a stop structure associated with the proximal end to prevent over-penetration of the fastener body into tissue, the stop structure bisecting the diameter of the fastener body. The stop structure may be offset from the diameter of the fastener body.

In one embodiment the receptacle is sized and configured to present the fastener to a fastener applier. There may also be a post positioned within the receptacle to releasably restrain the fastener. A pliable material may also be included within the receptacle to position a tip of the fastener in the pliable material to releasably restrain the fastener. The fastener may also be releasably restrained within the receptacle by friction between the fastener and the receptacle wall.

Yet an additional aspect of the invention provides devices, systems, and methods for installing a fastener to a fastener applier used for securing a prosthesis into a hollow body organ or blood vessel. The devices, systems, and methods comprise providing an apparatus for storing a fastener, the apparatus comprising a base structure, and at least one receptacle positioned within the base structure, the receptacle sized and configured to releasably store at least one fastener, providing a fastener applier for securing a prosthesis, the fastener applier comprising a handle assembly positioned at the caudal end of the fastener applier, a fastener applier shaft coupled to the handle assembly, and a fastener driver for advancing a fastener into the prosthesis and tissue, the fastener driver coupled to the fastener applier shaft at the cephalad end of the fastener applier shaft, the fastener driver including a housing and a release latch, wherein the release latch prevents premature release of the fastener from the fastener driver, positioning the fastener driver so as to allow the fastener driver to couple to releasably stored fastener, and coupling the fastener to the fastener applier. The step of coupling the fastener to the fastener applier may also include operating a motion control assembly positioned on the handle assembly to retract the fastener out of the receptacle and onto

the fastener driver.

In one embodiment , the receptacle is sized and conf igured to releasably secure at least o ne helical faste ner. The helical fastener may include a fastener body having a distal end for penetrating tissue in response to a force and a proximal end fo r releasably coupling the fastener body to the fastener applier, and a stop structure as sociated with the proximal end to prevent over - penetration of th e fastener body into tissue, the stop structure bisecting the diameter of the fasten er body. The stop structure may be offset from the diameter of the fastener body.

Other features an d advantages of the invention sha ll be apparent based upon the accompanying description, drawings, and claims.

Brief Description of the Drawings

Fig. 1 is a per spective view of one embodiment of a prosthesis deployment catheter show n positioned with in an abdominal aortic aneurysm.

Fig. 2 is a per spective view of one embodiment of the deployment of a prosthesis within the aneurysm of F ig. 1, with th e jacket partially retracted.

Fig. 3 is a per spective view of one embodiment of the deployment of a prosthesis within the aneurysm of F ig. 1, with the jacket fully retracted and showing radial expansion of the proximal end.

Fig. 4 is a per spective view of one embodiment of the completed deployment of a multi -lumen prosthesis within the aneurysm of Fig. 1.

Fig. 5 is a persp ective view of an alterna tive embo diment of the completed deployment of a s ingle lumen prost hesis within the aneurysm of Fig. 1.

Fig. 6 is a side view of the multi -lumen prosthesis assembly that emb odies features of the invention, the multi -lumen prosthesis assembly shown with lumen extensions.

Fig. 7A is a side view of the main body component o f the multi-lumen prosthesis assembly.

Fig. 7B is an enlarged view showing detail of the distal stent curved apices of the multi-lumen prosthesis shown in Fig. 7A.

Fig. 7C is a side view of one embodiment of the prosthesis septum, showing stitches and weaving to form the septum.

Fig. 7D is a side view of an alternative embodiment of the main body component of the multi-lumen prosthesis assembly of Fig. 7A, showing the main body prosthesis having a second lumen extending beyond the first lumen.

Fig. 8A is a section view of the distal end of the main body component of the multi-lumen prosthesis taken generally along line 8A-8A of Fig. 6.

Fig. 8B is a section view of the proximal end of the main body component of the multi-lumen prosthesis taken generally along line 8B-8B of Fig. 6.

Fig. 9A is a side view of a prosthesis lumen extension.

Fig. 9B is an enlarged view showing detail of the securing stent curved apices of the lumen extension shown in Fig. 9A.

Fig. 9C is a side view of one extension lumen coupled to the main body component of the multi-lumen prosthesis.

Fig. 9D is an enlarged view showing detail of the curved apices of both the securing stent of the lumen extension coupled to the distal stent of the main body prosthesis, as shown in Fig. 9C.

Fig. 10A is a side view of an alternative embodiment of the prosthesis lumen extension of Fig. 9A, and shows securing stents without deflected apices.

Fig. 10B is an enlarged view showing detail of the securing stents of the lumen extension shown in Fig. 10A.

Fig. 10C is a side view showing the alternative embodiment of the prosthesis lumen extension of Fig. 10A coupled to the main body component of the multi-lumen prosthesis.

Fig. 10D is an enlarged view showing detail of the securing stents of the alternative embodiment of the lumen extension coupled to the distal stent of the main body prosthesis, as shown in Fig. 10C.

Fig. 11 is a perspective view of a prosthesis deployment catheter that embodies features of the invention.

Fig. 12 is a side view of one embodiment of the proximal end of the deployment catheter of Fig. 11.

Fig. 13 is a side view of the proximal end of the deployment catheter of Fig. 11, and showing a jacket coverin g components of the deployment catheter.

Fig. 14A is a side view of the proximal end of the deployment catheter of Fig. 11, and showing the jacket covering the main body component of the multi-lumen prosthesis prior to deployment.

Fig. 14B is a perspective view of an alternative embodiment of the deployment catheter jacke t of Fig. 11 sh owing structural reinforcement.

Fig. 15 is a section view of the lumens in the central shaft deployment catheter taken generally along line 15-15 of Fig. 12.

Fig. 16 is a side view of the catheter tip and central shaft of the depl oyment catheter s howing the cathet er tip lumen and central shaft lumen.

Fig. 17 is a perspective view of the main body component of the multi -lumen p rosthesis positioned on the proxi mal end of the deployment catheter prior to dep loyment, and sho wing the first proximal retaining means in a compressed condition.

Fig. 18A is a sid e view of one emb odiment of a sutur e loop path around the main body component of the multi-lumen prosthesis.

Fig. 18B is a side view of an alternative embodiment of a suture loop path around the mul ti-lumen prosthesis of Fig. 18A, showing multiple suture loops.

Fig. 19 is a perspective view of the main body component of the multi -lumen p rosthesis positioned on the proxi mal end of the deployment catheter showing the first proximal retaining means released and the proximal end of the main body component expanded.

Fig. 20 is a side view of a portion of the distal end of the deployment catheter showing one embodiment of a first proximal releasing means and a first proximal release wire.

Fig. 21 is a side view of a portion of the proximal end of the deployment catheter showing detail of the first proximal release hub and central shaft lumens.

Fig. 22 is a side view of a portion of the distal end of the deployment catheter showing detail of one embodiment of the second proximal releasing means.

Fig. 23 is a side view showing detail of the stabilizing arms in a pre-deployment configuration, the proximal ends of the stabilizing arms being arched back generally toward a first proximal release hub.

Fig. 24 is a side view of the stabilizing arms of Fig. 23 in a pre-deployment configuration with the deployment catheter and multi-lumen prosthesis positioned within the descending aorta, and showing the proximal ends of the stabilizing arms coupled to the proximal end of the main body prosthesis.

Fig. 25 is a side view showing detail of stabilizing arms coupled to the proximal end of the main body prosthesis, showing the second proximal release wire stitched or otherwise extended through a stabilizing arm aperture and through the prosthesis material, releasably securing the stabilizing arms to the main body prosthesis.

Fig. 26 is a side view of the stabilizing arms of Fig. 23 in a post-deployment configuration with the deployment catheter and multi-lumen prosthesis positioned within the descending aorta, and showing the proximal ends of the stabilizing arms released from the proximal end of the main body prosthesis.

Fig. 27 is a section view of the proximal end of the deployment catheter shaft taken generally along line 27-27 of Fig. 23.

Fig. 28 is a side view of the distal end of the main body prosthesis positioned on the deployment catheter central shaft prior to deployment of the distal retaining means.

Fig. 29A is a side view of one embodiment of a suture loop path around the distal end of the multi-lumen prosthesis.

Fig. 29B is a side view of an alternative embodiment of a suture loop path around the distal end of the multi-lumen prosthesis of Fig. 29A, showing multiple suture loops.

Fig. 30 is a side view of the distal end of the main body component of the multi-lumen prosthesis positioned on the deployment catheter shaft of Fig. 28, showing the distal retaining means released

and the distal end of the main body component expanded.

Fig. 31 is a side view of a portion of the proximal end of the deployment catheter showing detail of the distal releasing means and central shaft lumens.

Fig. 32 is a side view of an alternative embodiment of the distal end of the main body prosthesis positioned on the deployment catheter central shaft prior to deployment of the distal retaining means.

Fig. 33 is a side view of the distal end of the main body component of the multi-lumen prosthesis positioned on the deployment catheter shaft of Fig. 32, showing the alternative distal retaining means released and the distal end of the main body component expanded.

Fig. 34 is a perspective view of a first side of the deployment catheter handle assembly that embodies features of the invention.

Fig. 35 is a perspective view of a second side of the deployment catheter handle assembly that embodies features of the invention.

Fig. 36 is a top view of the deployment catheter handle assembly of Fig. 34.

Fig. 37 is a section view of the deployment catheter handle assembly of Fig. 34 taken generally along line 37-37 of Fig. 36.

Fig. 38 is a section view of the deployment catheter handle assembly of Fig. 34 taken generally along line 38-38 of Fig. 36.

Fig. 39 is a top view of a portion of the deployment catheter handle assembly of Fig. 34 showing the jacket retraction means prior to jacket retraction.

Fig. 40 is a top view of a portion of the deployment catheter handle assembly of Fig. 39 showing the jacket retraction means after the jacket has been retracted.

Fig. 41 is a perspective view of a second side of one embodiment of a rack and pinion mechanism and a release system positioned within the deployment catheter handle assembly.

Fig. 42 is a perspective view of a second side of one embodiment of a rack and pinion mechanism and a release system

positioned within the deployment catheter handle assembly.

Fig. 43 is a perspective view showing detail of the release system positioned within the deployment catheter handle assembly.

Fig. 44A is a perspective view of a lumen extension deployment catheter that embodies features of the invention.

Fig. 44B is a perspective view of the lumen extension deployment catheter shown in Fig. 44A, and showing a stationary outer jacket and a hemostatic valve.

Fig. 45A is a side view of one embodiment of the proximal end of the lumen extension deployment catheter of Fig. 44.

Fig. 45B is a side view of an alternative embodiment of the proximal end of the lumen extension deployment catheter of Fig. 45A, and shows an optional distal retaining and releasing means.

Fig. 46A is a side view of a proximal section of the lumen extension deployment catheter of Fig. 45A, and showing a jacket covering the lumen extension positioned on the catheter shaft prior to deployment.

Fig. 46B is a side view of an alternative embodiment of a proximal section of the lumen extension deployment catheter of Fig. 45B, and showing a jacket covering the lumen extension positioned on the catheter shaft prior to deployment and including a distal retaining means.

Fig. 46C is a perspective view of an alternative embodiment of the lumen extension deployment catheter jacket of Fig. 44 showing structural reinforcement.

Fig. 47A is a section view of the lumen extension deployment catheter shaft of Fig. 45A taken generally along line 47A-47A of Fig. 45A.

Fig. 47B is a section view of an alternative embodiment of the lumen extension deployment catheter shaft of Fig. 45B taken generally along line 47B-47B of Fig. 45B.

Fig. 48A is a side view of one embodiment of a suture loop path around the proximal end of the lumen extension.

Fig. 48B is a side view of one embodiment of a suture loop path around the distal end of the lumen extension.

Fig. 48C is a side view of an alternative embodiment of a suture loop path around the proximal or distal end of the lumen extension shown in Figs. 48A and 48B, and shows multiple suture loops.

Fig. 49A is side view of the lumen extension deployment catheter handle assembly of Fig. 44.

Fig. 49B is a side view of an alternative embodiment of the lumen extension deployment catheter handle assembly of Fig. 44, and showing and additional slide knob for an optional distal releasing means.

Fig. 50 is top view of the lumen extension deployment catheter handle assembly of Fig. 44.

Fig. 51 is a perspective view of one embodiment of the release system positioned within the handle assembly of the lumen extension deployment catheter.

Fig. 52 is an enlarged perspective view of one embodiment of a helical fastener that can be used in association with a fastener tool or device shown in Fig. 53.

Fig. 53 is a perspective view of a fastener tool that embodies features of the invention.

Fig. 54 is a perspective view of the handle assembly of the fastener tool of Fig. 53.

Fig. 55 is a perspective view of a steerable guide device that embodies features of the invention.

Fig. 56 is a perspective view of the handle assembly of the steerable guide device of Fig. 55.

Fig. 57 is a perspective view of an obturator or dilator that may be used in conjunction with the steerable guide device of Fig. 55.

Fig. 58 is a perspective view of one embodiment of a prosthesis deployment catheter shown positioned with in an abdominal aortic aneurysm.

Fig. 59 is a perspective view of the deployment of the main body component of the multi-lumen prosthesis within the aneurysm of Fig. 58, with the jacket partially retracted.

Fig. 60 is a perspective view of the deployment of the main

body component of the multi -lumen prosthesis within the aneurysm of Fig. 58, with the jacket fully retracted but prior to the release of the proximal or distal retaining means.

Fig. 61 is a perspective view of the deployment of the main body component of the multi -lumen prosthesis within the aneurysm of Fig. 58, with the jacket fully retracted but prior to the release of the proximal or distal retaining means and showing an alternative embodiment of the distal retaining means.

Fig. 62 is a perspective view of the deployment of the main body component of the multi -lumen prosthesis within the aneurysm of Fig. 58, and showing the first proximal retaining means released and the proximal end of the main body component expanded.

Fig. 63 is a perspective view of the deployment of the main body component of the multi -lumen prosthesis within the aneurysm of Fig. 58, and showing a second guide wire positioned through the main body prosthesis lumen.

Fig. 64 is a perspective view of the deployment of the main body component of the multi -lumen prosthesis within the aneurysm of Fig. 58, and showing the steerable guide and obturator positioned on the second guide wire and through the main body prosthesis lumen.

Fig. 65 is an enlarged perspective view of the deployment of the main body component of the multi-lumen prosthesis within the descending aorta, and showing the steerable guide device and the fastener tool just prior to fastening a helical fastener through the prosthesis material and into tissue.

Fig. 66 is an enlarged perspective view of the deployment of the main body component of the multi-lumen prosthesis within the descending aorta, and showing the steerable guide device and the fastener tool just after fastening a helical fastener through the prosthesis material and into tissue.

Fig. 67 is a perspective view of the deployment of the main body component of the multi -lumen prosthesis within the aneurysm of Fig. 58, and showing the deflected end of the steerable guide device and the fastener tool after being repositioned for deployment of an additional helical fastener.

Fig. 68 is an enl arged perspective view of the depl oyment of the main body component of the multi-lumen prosth esis within the descending aorta, and showing one e mbodiment of a fa stener deployment pattern.

Fig. 69 is a perspective vi ew of the deployment of a lumen extension component of the multi -lumen prosthesis within the aneurysm of Fig. 58, a nd showing the lumen extension catheter being positioned partially within a prosthesis lumen.

Fig. 70 is a perspective view of the deploymen t of the lumen extension component of the multi-lumen prosthesis within the aneurysm of Fig. 58, and showing t he jacket retracte d from the lume n extension deployment catheter and prior to the release of a proximal retaining means.

Fig. 71 is a perspective view of the deployment of the lumen extension component of the multi-lumen prosthesis within the aneurysm of Fig. 58, and showing t he lumen extensio n coupled to an d fully expanded wi thin a lumen of the main body com ponent after the release of the proximal retaining means.

Fig. 72 is a perspective view of the deployment of the main body component of the multi -lumen prosthesis within the aneurysm of Fig. 58, and show ing the lumen ext ension deployment catheter removed and the stabiliz ing arms of the main bod y depl oyment catheter released.

Fig. 73 is a perspective view of the deployment of the main body component of the multi -lumen prosthesis within the aneurysm of Fig. 58, and showing the distal retaining means released and the distal end of the main body prosthesis expanded.

Fig. 74 is a perspective view of the deployment of the main body component of the multi -lumen prosthesis within the aneurysm of Fig. 58, and sho wing the withdraw al of the re jacketed main body deployment catheter over the fist guide wire.

Fig. 75 is a perspective view of the deployment of a second lumen extension component of the multi-lumen prosthesis within the aneurysm of Fig. 58, and showing t he lumen extensio n catheter being positioned partially within a prosthesis lumen.

Fig. 76 is a perspective view of the deployment of the second lumen extension component of the multi-lumen prosthesis within the aneurysm of Fig. 58, and showing the jacket retracted from the lumen extension deployment catheter and prior to the release of a proximal retaining means.

Fig. 77 is a perspective view of the deployment of the second lumen extension component of the multi-lumen prosthesis within the aneurysm of Fig. 58, and showing the second lumen extension coupled to and fully expanded within a lumen of the main body component after the release of the proximal retaining means.

Fig. 78 is a perspective view of one embodiment of the completed deployment of the multi-lumen prosthesis within the aneurysm of Fig. 58.

Fig. 79A is an enlarged perspective view of an alternative embodiment of a helical fastener that can be used in association with a fastener tool or device shown in Fig. 53.

Fig. 79B is an enlarged top view of the alternative fastener of Fig. 79A showing a "D" shape.

Fig. 80 is an enlarged perspective view of the deployment of the main body component of the multi-lumen prosthesis within the descending aorta, and showing the steerable guide device and the fastener tool having an alternative fastener driver just prior to fastening the helical fastener of Fig. 79A through the prosthesis material and into tissue.

Fig. 81 is an enlarged perspective view of the fastener driver and fastener of Fig. 80, and showing the fastener rotating off of the fastener carrier.

Fig. 82A is an enlarged side view of the fastener driver of Fig. 80, and showing a fastener positioned on the fastener carrier and within a threaded fastener housing, and also showing the fastener latch feature.

Fig. 82B is an enlarged side view of the fastener driver of Fig. 80, and showing a fastener on the carrier and rotating off the carrier and showing the pivoting of the fastener latch.

Fig. 82C is an enlarged side view of the fastener driver of

Fig. 80, and showing a fastener positioned on the fastener carrier and within a threaded fastener housing, and also showing an alternative fastener latch feature.

Fig. 83 is a perspective view of one embodiment of a fastener cassette with fasteners releasably positioned with a fastener receptacle.

Fig. 84 is a perspective view of an alternative embodiment of a fastener cassette of Fig. 82.

Fig. 85 is a perspective view showing the fastener tool positioned on a fastener cassette for removal of a fastener from the cassette and positioning the fastener within the fastener driver.

Fig. 86 is a perspective view showing the fastener tool with a fastener positioned in the fastener driver and ready for deployment.

Detailed Description of the Invention

This Specification discloses various catheter-based devices, systems, and methods for delivering and implanting radially expandable prostheses in the body lumens. For example, the various aspects of the invention have application in procedures requiring the repair of diseased and/or damaged sections of a hollow body organ and/or blood vessel. The devices, systems, and methods that embody features of the invention are also adaptable for use with systems and surgical techniques that are not necessarily catheter-based.

The devices, systems, and methods are particularly well suited for treating aneurysms of the aorta that primarily occur in the abdominal region, usually in the infrarenal area between the renal arteries and the aortic bifurcation, as well as aneurysms that also occur in the thoracic region between the aortic arch and renal arteries. For this reason, the devices, systems, and methods will be described in this context. Still, it should be appreciated that the disclosed devices, systems, and methods are applicable for use in treating other dysfunctions elsewhere in the body, which are not necessarily aorta-related.

I. Overview

Fig. 1 depicts a portion of the descending aorta and shows an abdominal aortic aneurysm 20. For the purposes of illustration, Fig. 1 shows the targeted site for delivery and implantation of a prosthesis as being within the abdominal aortic aneurysm 20. It is to be appreciated that the targeted site can also be elsewhere in the body. In the illustrated arrangement, the prosthesis takes the form of an endovascular graft.

In order to provide a consistent orientation for the devices, systems, and methods described herein, the terms proximal or cephalad will be used to describe a relation or orientation toward the head or heart, and the terms distal or caudal will be used to describe a position or orientation toward the feet or away from the heart. Therefore, the devices, systems, and methods can be described as having a proximal or cephalad component and a distal or caudal component. The use of these terms also applies to the implantation apparatus as used in the implantation process described, i.e., the deployment catheter handle is distal or caudal as the handle of the deployment catheter is oriented toward the feet and away from the heart.

The proximal or cephalad end 202 of a prosthesis deployment catheter 200 can be seen in Fig. 1 positioned over a first guide wire 30 (the guide wire being previously positioned) and extending through at least a portion of the abdominal aortic aneurysm 20. The deployment catheter 200 carries the main body of the prosthesis 120 (see Fig. 2), which is placed at the targeted site, e.g., by radial expansion of the main body prosthesis 120 (see Fig. 3). After expansion of the main body prosthesis 120, one or more fasteners 402 (see Fig. 4) may be introduced by a fastener device 400 to anchor the proximal end 108 of the main body prosthesis, in place.

Fig. 2 depicts the initial stage of the main body prosthesis 120 deployment at the targeted site. While the deployment method can vary, in the illustrated embodiment, the delivery catheter 200 has a movable jacket or outer sheath 210, which overlays the main body prosthesis 120. When the outer jacket 210 is pulled distally, or in a caudal direction, the main body prosthesis 120 is exposed but may

remain in an unde ployed configuration until rele asing means has been activated. Once the releasing means has been activated, the main body prosthesis or a portion(s) of the main body prosthesis 120 is free to radially expand, thereby enlarging to contact at least a portion of the internal walls of the blood vessel. The prosthesis deployment process is continued, including the deployment of one or more lumen extensions, until a multi-lumen or bifurcated prosthesis 100 is fully deployed within the vessel, as can be seen in Fig. 4 and will be described in greater detail later.

It is to be understood that the terms prosthesis and prostheses both can mean an independent component, or multiple components coupled together, or multiple components not necessarily coupled together. The prosthesis may be either coupled together at or near the targeted site, or exterior the body, or a combination of both.

In a desirable embodiment, the prosthesis is a multi-lumen prosthesis. In an alternative embodiment, the prosthesis is a straight prosthesis. The prosthesis 100 may be self-expanding, or, the prosthesis 100 can utilize an expanding member, such as a balloon or mechanical expander. Fig. 4 depicts a completely deployed multi-lumen or bifurcated prosthesis 100 that is sized and configured to be positioned within the aorta and extend across the aneurysm and into the contralateral iliac artery and the ipsilateral iliac artery. Fig. 5 depicts a completely deployed straight prosthesis 50.

It is to be appreciated that one or more fasteners 402 can be introduced into the multi-lumen prosthesis 100 to anchor the main body 120 and/or lumen extensions 140 in place at different times or at the same time during the procedure.

II. General Methods of Endovascular Implantation

The prosthesis or prostheses 100 as just described lend themselves to implantation in a hollow organ in various ways. The prosthesis may be implanted using catheter-based technology via a peripheral intravascular access site, such as in the femoral artery, optionally with the assistance of image guidance. Image guidance

includes but is not limited to fluoroscopy, ultra sound, magnetic resonance, computed tomography, or combinations thereof. Alternatively, the prosthesis can be implanted, e.g., in an open chest surgical procedure.

Figs. 58 to 78 show a representative embodiment of the deployment of a prosthesis of the type shown in Fig. 4 by a percutaneous, catheter-based procedure. Percutaneous vascular access is achieved by conventional methods into the femoral artery, for example.

The implantation of the multi-lumen prosthesis 100 is first described here in a number of general steps. The multi-lumen prosthesis and each of the various tools used to implant the prosthesis are then described with additional detail below. The multi-lumen prosthesis 100 is described in section III and the various implantation apparatus are described in section IV. Additionally, the general implantation steps are then described again with additional detail below in section V.

A first implantation step can be generally described as deploying the main body 120 of the prosthesis. The deployment catheter 200 is positioned within the aortic aneurysm 20 and the main body of the prosthesis is allowed to deploy. Proximal and distal retaining means hold the main body prosthesis in a predetermined relationship to the proximal end 202 of the deployment catheter. By activating a proximal releasing means, the proximal end 108 of the main body prosthesis 120 may be partially or fully released from the deployment catheter shaft so as to allow the proximal stent 130 to expand to contact the aorta or a portion of the aorta. At this step the prosthesis may not be fully released from the deployment catheter. The main body prosthesis 120 may be attached to the deployment catheter 200 through a second proximal retaining means. The proximal end 108 or other areas of the main body prosthesis 120 is fastened to the vessel wall to resist axial migration of the prosthesis.

Next, an extension catheter 350 carrying a first prosthesis lumen extension 140 is guided through the vasculature and to the main body prosthesis 120. The first lumen extension is telescopically

fitted within the second lumen 128 of the main body prosthesis 120 and allowed to radially expand. The extension catheter is then removed, leaving the lumen extension 140 coupled to the main body prosthesis 120 and extending into the contralateral iliac artery.

If the main body prosthesis 120 is attached to the deployment catheter 200 through a second proximal retaining means, a second releasing means is activated to allow the proximal end 108 of the main body prosthesis 120 to release from the deployment catheter shaft 216. The distal releasing means is then activated, allowing the distal end 110 of the main body prosthesis 120 to release from the deployment catheter shaft 216 and radially expand. The deployment catheter 200 is then removed from the body.

Lastly, the extension catheter 350 carrying a second prosthesis lumen extension 140 is guided through the vasculature and to the main body prosthesis 120. The second lumen extension 140 is telescopically fitted within the first lumen 126 of the main body prosthesis and allowed to radially expand. The extension catheter 350 is then removed, leaving the lumen extension 140 coupled to the main body prosthesis 120 and extending into the ipsilateral iliac artery. The multi-lumen prosthesis 100 is now fully deployed across the aortic aneurysm.

III. Multi-Lumen Prosthesis Assembly

Fig. 6 shows a multi-lumen prosthesis assembly 100 that embodies features of the invention. In the illustrated embodiment, the multi-lumen prosthesis assembly 100 comprises a main body component 120 and at least one lumen extension 140, desirably two lumen extensions.

The main body component 120 is sized and configured to fit within a hollow body organ and/or a blood vessel. As described in this Specification, the targeted site of deployment is within the aorta adjacent the renal arteries, as will be described in greater detail later. However, this targeted site of deployment is selected for purposes of illustrating the features of the prosthesis 100, and

is not intended to be limiting.

Referring to Fig. 7A, the main body component 120 has a proximal and distal end 108, 110, and includes an interior communicating with a proximal opening 122 for fluid flow into or from the prosthesis. The main body component 120 includes a septum 124 within its interior. The length of the septum 124 within the prosthesis 120 can vary. In the illustrated embodiment, the septum 124 does not extend along the entire length of the main body component 120, but is spaced a distance from the proximal opening 122. In the illustrated arrangement, the septum 124 comprises a longitudinal seam. The seam can be formed by coupling the opposing surfaces together (i.e., the front and back) of the prosthesis material 112 (which is typically a fabric) by sewing, heat bonding, stitching or weaving, for example, or any combination. The coupling of the opposing surfaces together thereby creates a septum or shared, common wall between two lumens, the first lumen 126 and the second lumen 128 (see Figs. 8A and 8B). Typically the seam 124 would be located along the midline of the main body to create two equally sized lumens 126 and 128. However, the location of the seam 124 could be moved, if different sized lumens were desired. In one embodiment shown in Fig. 7C, the septum 124 is formed by a stitch(s) 131 at the septum's proximal end 121, a stitch(s) 133 at the septums distal end 123, and a weave(s) 135 in-between the stitches 131, 133 at the septum's proximal end 121 and distal end 123. The combination of stitches and weaving, for example, provides added stability to the septum 124.

The septum 124 transforms at least a portion of the interior of the main body component 120 into the multi-lumen flow channel configuration. In the illustrated embodiment, the multi-lumen flow channel configuration comprises dual first and second interior lumens 126 and 128. Due to the septum 124, the dual first and second interior lumens 126 and 128 of the multi-lumen flow channel configuration do not form branched or divergent lumens. The shared common wall or seam (the septum 124) prevents divergence and maintains the lumens 126 and 128 in a non-divergent, generally parallel flow relationship (as Figs. 8A and 8B show).

In the illustrated arrangement, the septum 124 runs generally along the mid-line of the main body component 120, making the multi-lumen flow channel configuration within the main body component 120 essentially symmetric. However, it should be appreciated that the septum 124 could form a non-symmetric multi-lumen flow channel configuration. It should also be appreciated that multiple septums can be present within the interior, transforming the interior of the main body component 120 into several flow lumens. The length of the septum can vary. In a representative embodiment, the septum 124 is typically greater than 10 mm in length and not less than 5 mm in length.

In the illustrated embodiment, the first lumen 126 defines a flow channel sized and configured to reach a targeted destination or source spaced a defined distance from the proximal opening 122, while the truncated second lumen 128 communicates with generally the same targeted destination as the proximal opening 122 of the main body component 120 itself. Furthermore, the septum 124 is sized and configured to accommodate the coupling of a flow channel extension 140 to the first lumen 126 and to the truncated second lumen 128, to likewise extend their reach to another targeted source or destination spaced from the proximal opening 122, if desired.

The second lumen 128 is truncated along at least a portion of the septum 124. As a result, the distal opening 127 of the first lumen 126 can be said to extend beyond the distal opening 129 of the second lumen 128. Still, the shared common wall (the septum 124) prevents divergence and maintains the lumens 126 and 128 in a non-divergent, generally parallel flow relationship. It is to be appreciated that the first and second lumens 126, 128 may be reversed, i.e., the second lumen 128 may extend beyond the first lumen 126 (see Fig. 7D).

In this arrangement, the multi-lumen prosthesis assembly 100 desirably includes a first and second flow channel lumen extension 140 (see Fig. 6). The first and second lumen extensions 140 desirably comprise the same construction, i.e., they are duplicates of each other. Referring to Fig. 9A, the lumen extension 140 includes a

proximal end 142 that is sized and configured t o be telescopically fitted within the first lumen 126 and/or the trunca ted second lumen 128 of the main b ody component 120. The distal end 1 44 of the lumen extension 140 is s ized and configured to extend the re ach of the first lumen 126 and the truncated s econd lumen 128 to another targeted destination or source spaced a defined distance from the main body component proximal opening 122. As a result, a portion of th e extended second lumen 128 is joined to the first lumen 126 by the septum 124, and a portio n of the extended second lumen 128 is not joined by the septum 124 to the lume n extension 140 of the first lumen 126.

Both the first lumen 126 and the truncated second lumen 128 of the main body component 120, whi ch is joined by t he septum 124 to the first lumen 126, provide an in terface region or socket that is fully enclosed wit hin the body of the main body component 120 itself. The first lumen 1 26 and the trunca ted second lumen 128 are therefor e not prone to ki nking or twistin g or other kind s of moveme nt independent of th e main body compo nent 120. Passage of a guide wire through the firs t lumen 126 or the second lumen 128 can occur unimpeded.

Being telescopically fitted within the interface region or socket and enclosed within the main body component 1 20, the mechanical properties of th e lumen extensio n 140 are suppl emented by the structural support and integrity of the main bo dy component 120 itself, and vice versa. Coupled toge ther, the main body component 120 and the lumen ext ension 140 provide enhan ced resistance to migration and/or separation of the lum en e xtension 140 from the main bo dy component 120. Sea ted within the en closed interface r egion, the lumen extension 140 is peripherally sealed within the main body component 120 to resist lea ks or see page of fluids around the lumen extension 140. The septum 124 can be tapere d, curved, wavy, or otherwise non - linear to enhance the connection between the lumen extension 140 and the main body component 120.

In one illustrated use (see Fig. 3), the main b ody component 120 can be deployed in the aorta in t he region of the

bifurcation of t he first and se cond iliac, or ipsilateral and contralateral iliac arteries. When the main body prosthesis 120 is deployed, both the first lumen 126 a nd the second lumen 128 remains in communication with the aorta. After the main body component 120 is deployed, the first lumen extension 140 can be fitted within the distal opening 12 7 of the first lumen 126, and t he second lumen extension 140 can be fitted withi n the distal o pening 129 of th e second lumen 128, so that the distal end 144 of the first extension 140 can be sized to reach into t he first iliac of the bifurcation, while the distal end 144 of the second extension 140 can reach into the second iliac of the bifurca tion (see Fig. 4). In thi s arrangement, the first lumen exten sion 140 of lumen 126 serves as a first lumen or ipsilateral lumen of the prosthesis 100, and the lumen extension 140 of the second lumen 128 serves as a second lumen or contralateral lumen.

The ma in body com ponent 120 may in clude a proximal sealing stent 130 at its proximal end 10 8, which may ext end beyond th e prosthetic material 112 (see Fig. 7A). The proximal stent 130 orients the main body pros thesis 120 within the lumen and aids in maintainin g the position of the main body pr osthesis 120 in the aorta withou t obstructing the n ormal blood flow into the re nal arteries. The proximal sealing stent 130 may be a self -expanding zigzag or diamond shaped stent, for example, and is desirably sewn inside t he prosthesis material 112, although the stent may be outside, or may be wrappe d between two layers of prosthesis material 112, for example.

Typically, this r egion of the aort a (proximal neck of the aneurysm just below the renal arteri es) is also one a rea where one or more fasteners 40 2 may be introdu ced by a fastene r device 400 t o anchor the prosthe sis 100 in place (see Fig. 4). Ho wever, it should be noted that ot her areas through out the main bod y 120 and lume n extensions 140 can also be fastened in plac e. It is desirable that this region of the main body componen t 120 be sized an d configured for the receipt and re tention of fastene rs, e.g., the size and spacing o f diamond or zigzag stent patterns to specially accommodate the placement of fast eners; and/or the use of woven fi bers with an "X-

pattern" or a "sinusoidal pattern" to specially accommodate placement of fasteners; and/or to fold over the prosthetic material 112 to form multiple layers, to reinforce the prosthesis in the region where fasteners 402 are placed; and/or the use of denser weave patters or stronger fibers from, e.g., Kevlar™ material or Vectran™ material or metallic wire woven alone or interwoven with typical polyester fibers in the region were fasteners are placed. It may also be desirable to fluoroscopically indicate this region of the prosthesis with radiopaque markers 132 on the prosthetic material 112 or proximal sealing stents 130 to aid in positioning the fastening devices.

Additional stents may be utilized throughout the main body component 120. Desirably, a minimal number of stents would be utilized within the main body component 120.

The multiple lumens 126 and 128 in the main body component 120 may typically be supported with distal stent rings 134 sewn or otherwise attached to the inside or outside of the prosthetic material 112. The proximal apices 136 of the stent rings 134 desirably are angled or curved inwardly (see Fig. 7B). The inward angle provides a retentive feature when the lumen extension 140 is positioned within a first or second lumen (see Fig. 10 B). Alternative retentive features may also be used, such as hooks, barbs, loops of fabric or loops/folds of graft material or pockets in graft material, for example. Ideally, the distal stent rings 134 in one lumen 126 are staggered axially in position with the stent rings 134 in the other lumen 128, so that they do not overlap each other when the main body component 120 is radially compressed prior to deployment.

Rotational orientation of the main body component 120 within the vessel lumen or hollow body organ is accomplished with additional radiopaque markers 137 and 138 attached to the main body prosthesis 120 for visualization under fluoroscopy. Typically, these markers may be attached to the prosthetic material 112. Still, the markers 137 and 138 may be attached to the proximal sealing stent 130 or distal stent rings 134 instead of or in addition to the prosthetic material 112 to help fluoroscopically determine the location of all prosthesis openings. The radiopaque markers typically are in the form

of marker bands, tight wound coils, or wire made from radiopaque materials such as platinum, platinum/iridium, tantalum, or gold for example.

Desirably, one or more markers 137 , 138, are longer than the other, and a re at tached on o pposite sides of the main bod y component 120 with the longer marker s 137 aligned on t he side with the first lumen 126 a nd the shorter ma rkers 138 aligned on the side with the second lumen 128, for example. In an alternati ve embodiment the markers could be aligned with the septum. The mark ers 137 and 138 enable the clinician to determine the desired rotational orientation of the main body prosthesis 120 in the delivery sys tem so that, upon deployment, the first distal opening 127 and the second distal opening 128 are aligned wi th the desired ili ac arteries. The proximal markers 132 may also be included to enabl e the clinician to determine the position of the p roximal end 108 o f the main body component 120 in relation to the fixation point of the aorta. Additionally, distal markers 139 may be included to a id in the locati on of the distal openings 127, 129, and the insertion of the lumen extension 140. Insertion depth marker(s) 125 may be attached near the septum 124, o r may be attached to the se ptum, or may be attached to the prosthesis material 112, for example, to indicate the location of and insertion depth for the lumen extension 140.

As previously des cribed, the main body 120 (and the lumen extension 140) desirably utilizes a prosthetic mat erial 112. The material 112 of the main body 120 may carry individual self -expanding, zigzag or diamond type stent rings, for example. The stent rings need not be attached to one another throughout the main body prosthesis 120. However, it may be desira ble in certain locations within th e prosthesis structure 120 to have a ttachments between the individual stent rings to provide stability and/or additional radial support.

As previously sta ted, the septum 1 24 is formed by s ewing, heat bonding, stitching, or weaving opposing surfaces (i.e., the front and back) of the prosthetic material 112 of the main body component 120 together. In the region of th e septum 124, the stent rings 13 4 extend from the septum 124 about the formed lumen, but do not enter o r

otherwise interru pt the septum 1 24 itself. The septum 124 is continuous and is formed separate from the supporting structure of stent rings 134.

The individual distal stent rings 134 allow for longitudinal main body prosthesis 120 compliance while maintainin g radial support of the prosthesis lumens. This technica l feature allows the prosthesis to more readily accommodate changes in vessel/aneurysm morphology.

The stents can be made, e.g., from Nitinol®. Still, other materials, manufacturing methods and designs can be u sed. Each of t he stents may be sewn onto prosthetic material 112. In certain locations it is desired to h ave the stents attached to the outer diameter of the prosthetic material 112. Still, i t is also contem plated that the stents could be attac hed to the inner diameter of the prosthetic material 112.

In the illustrated embodiment, the prosthetic material 112 is woven polyeste r, and the attac hment of the ste nts is made wit h polyester suture. However, it is also contemplated that other attachment means could be utilized to secure the stents to the prosthetic material 112. These means include bonding; capturing the stents between two layers of prosthetic mat erial 112; and incorporating the stents directly into the woven prosthetic material 112.

As seen in Fig. 9A, the lumen extension 140 has at least one spiral stent 1 46 positioned along at least a porti on of the length of the extension and attached to t he outside of pro sthetic material 112 to provide stability and/or additional radial supp ort. However, as in the main body component 120, it is contemplated that the stent 146 could also be plac ed on the inside of the prosthetic material 112, or the spiral stent 146 could be captured between two layers of prosthetic material (not shown). The prosthetic layer 112 could be a continuous tube or non -tubular. The prosthetic material 112 could cover the entire lumen extension 1 40 or the pro sthetic material 112 could cover only a portion of the lumen extension. Furthermore, as previously discussed, the spir al stent 146 need not be one continuous

stent along the length of the extension. The addition of the spiral stent 146 to the lumen extension 140 aids in the deployment of the lumen extension and allows for longitudinal compliance while maintaining radial support of the lumen within the lumen extension 140. Typically, radiopaque extension markers 148 are used on each end of the extension 140 to aid in the visualization of the placement of the lumen extension 140 within the lumen of the first distal opening 127 and the second distal opening 129 of the main body component 120.

As shown in Figs. 9A through 9D, the engaging stent or stents 150 in the lumen extension 140 can be sized, configured, and arranged to engage the stent rings 134 in the first lumen 126 and the second lumen 128 of the main body 120. The distal apices 147 of at least one engaging stent 150 are angled outwardly to engage the mating distal stent 134 on the main body component 120 (seen particularly in Figs. 9B and 9D). This engagement prevents the lumen extension 140 from moving or migrating axially in relation to the first lumen 126 and the second lumen 128 after the lumen extension 140 has been deployed. In an alternative embodiment shown in Figs. 10A through 10D, the spiral stents 146, which are attached to the outside of the lumen extension 140, may engage with the distal stents 134 of the main body 120 without being angled outwardly. In either of these embodiments, additional features may be included with the main body 120 or the lumen extensions 140 to help prevent the lumen extension 140 from moving or migrating axially in relation to the main body 120, such as hooks, barbs, loops of fabric or loops/folds of graft material, or pockets in graft material, for example.

During use (see Fig. 58), the deployment catheter 200 is navigated over the guide wire 30 through an iliac to the desired location within the aorta near the renal arteries. The catheter 200 carries the main body component 120 of the multi-lumen prosthesis system 100 in a radially reduced configuration. At the targeted site, the retaining jacket 210 is retracted which allows the distal stent 134 of the second lumen 128 to radially expand into the position shown in Fig. 60. The distal stent 134 of the first lumen 126 and the proximal stent 130 are not allowed to expand until releasing means

have been activated.

As Figs. 69 and 70 show, the first lumen extension 140 is carried in a radially compressed condition by an over-the-wire extension catheter 350 coming from the contralateral iliac, for example. The catheter 350 deploys the first lumen extension 140, such that the proximal end 142 of the lumen extension 140 is telescopically received within the second lumen 128 of the main body component 120 and the distal end 144 extends into the contralateral iliac, as Fig. 71 shows. The second lumen extension 140 is then carried in a radially compressed condition by the extension catheter 350 coming from the ipsilateral iliac, for example. The extension catheter 350 deploys the second lumen extension 140, such that the proximal end 142 of the lumen extension 140 is telescopically received within the first lumen 126 of the main body component 120 and the distal end 144 extends into the ipsilateral iliac, as Fig. 77 shows. Only when each lumen extension 140 is telescopically received within the first lumen 126 and second lumen 128 of the main body component 120, a bifurcated prosthesis 100 is formed with divergent lumens, as seen in Fig. 78.

IV. Implantation Apparatus

1. Prosthesis Deployment Catheter

Fig. 11 shows a prosthesis deployment catheter 200 having features of the invention. The purpose of the catheter 200 is to (i) contain and/or restrain the main body prosthesis 120 prior to its deployment (see Fig. 14A), (ii) deliver the main body prosthesis 120 through the vasculature to a desired location within the body, e.g., a hollow body organ or a blood vessel (see Fig. 1), and (iii) controllably deploy the main body prosthesis 120 in the desired location (see Figs. 2 and 3), including maintaining a stable position of the main body prosthesis 120 in a partially deployed condition while the main body prosthesis is fastened to the vessel wall. In the illustrated embodiment, the proximal end 202 of the catheter 200 is shown positioned over a guide wire 30 in a body lumen (see Fig. 1). The catheter 200 carries the main body prosthesis 120 in a radially reduced configuration to the targeted site. At the targeted site, the

catheter 200 rel eases the radial ly reduced prost hesis 120, which expands radially (see Figs. 2 and 3). After p artial or complete expansion or deplo yment of the main body prosthesis 120, one or mor e fasteners 402 are desirably introduced by a fastener device 400 to anchor the main b ody prosthesis 120 in place. The fasteners 402 may also serve to provide apposition of the prosthesis material 112 to the hollow body organ or vessel wall and to seal and/o r repair a fluid leak. Further details of the fastene r device and faste ner can be found in section three (3) below.

As prev iously des cribed, the prost hesis 100 can be sized and configured to be either straight or bifurcated form. Fig. 4 depicts a complet ely deployed bifu rcated prosthesis 100. Fig. 5 depicts a completely deployed straight prosthesis 50.

For the purposes of i llustration, Fig. 1 shows the targeted site as being wi thin an abdominal aortic aneurysm. Of course, the targeted site can be elsewhere in the body.

As shown in Figs. 11 through 14B, the catheter 200 comprises an inne r assembly 208, an outer jacket 21 0, a nd a handl e assembly 212. These components will now be individu ally described in greater detail.

A. The Inner Assembly

In the illustrate d embodiment (see Figs. 12 through 14B), the inner assembly 208 comprises a central shaft 216, which functions as a ca rrier for the main body p rosthesis 120, pr oximal and distal retaining means 2 18, 220, and a c atheter tip compo nent 222. The proximal retaining means 218 desi rably comprises a first proximal retaining means 2 24 and a second p roximal retaining means 226. T he first proximal r etaining means 2 24 desirably ret ains at least a portion of the m ain body prosthes is 120 in a radi ally compressed, and/or partially radially expanded condition prior to deployment and prior to fastenin g the main body p rosthesis 120 to the vessel wall. The second proxi mal retaining me ans 226 desirabl y functions to stabilize the de ployed proximal sealing stent 13 0 by preventing longitudinal and to a limited extent rotational movement. Each of the first and second proximal retaining means a lso desirably include a co-

acting releasing means or mechanism 228, 230 for maintaining the first or second proximal retaining means 224, 226 in a desired relationship with the main body prosthesis 120 prior to activation. The distal retaining means or mechanism 220 also desirably includes a releasing means or mechanism 232 for activating/releasing the distal retaining means or mechanism 220. The releasing means may comprise a wide variety of devices, such as wire or wires, sutures, magnetics, or fluids, and may include sliding, pulling or pushing, for example.

i. The Central Shaft

In the embodiment shown in Figs. 13 and 14A, the central shaft 216 and the proximal and distal retaining means 218, 220 are located within the confines of the outer jacket 210. In this respect, the outer jacket 210 functions as an enclosure for the main body prosthesis 120 on the carrier (see Fig. 14A). In this arrangement, the catheter tip component 222 is attached to the proximal end of the central shaft 216, and the proximal end of the outer jacket 210 terminates adjacent the catheter tip component 222. Thus, the catheter tip component 222 extends outward beyond the outer jacket 210. The central shaft 216, the proximal and distal releasing means 228, 230, 232, and the outer jacket 210 may be coupled to the handle assembly 212 at the proximal end of the catheter handle assembly 212 (see Fig. 11). As can be seen in Fig. 14A, the main body prosthesis 120 is contained in a cavity 234 defined between the central shaft 216 and the outer jacket 210 in the proximal section of the deployment catheter 200.

The central shaft 216 extends from the handle assembly 212 to the catheter tip component 222. The central shaft 216 may be made, e.g., from stainless steel or other suitable medical materials including other metals or polymers. The central shaft 216 comprises at least one lumen, desirably more than one lumen, and more desirably four lumens.

One lumen may be described as the central lumen 236 (see Fig. 15), with an inner diameter between .010 and .120 inches, desirably between .020 and .060 inches and most desirably between .030 and .050 inches. As described, the central lumen 236 allows for the

insertion of the guide wire 30 up to 0.038" diameter. The catheter tip component 222 also desirably has at least one lumen 238 (see Fig. 16) configured to align with at least one lumen within the central shaft 216. This lumen 238 allows for the insertion of the guide wire 30 through the central shaft 216 and through the catheter tip component 222. Typically this lumen 238 will have an inner diameter between .010 and .120 inches, desirably between .020 and .060 inches and most desirably between .030 and .050 inches.

ii. Catheter Tip

Desirably, the catheter tip component 222 is flexible and has a long, tapered proximal end 240 and a shorter, tapered distal end 242. The maximum diameter of the catheter tip component 222 is approximately the same as the outside diameter of the proximal end of the outer jacket 210. The proximal end 240 of the catheter tip component 222 provides a smooth tapered transition from the lumen 238 containing the guide wire 30 to the proximal edge of the outer jacket 210. This feature aids in catheter insertion and navigation through tortuous anatomy over the guide wire 30. The tapered section on the distal end 242 of the catheter tip component 222 prevents the catheter tip component 222 from inadvertently engaging the main body prosthesis 120, portions of the surrounding anatomy, or an introducer sheath or the like during removal of the deployment catheter 200 from the body.

iii. Proximal Retaining Means

a. First Proximal Retaining Means

As can be seen in Figs. 17 through 19, in the illustrated embodiment, the first proximal retaining means 224 comprises at least one suture, or sutures, 252 and/or equivalent structures, which are coupled to the prosthetic material 112, or one or more stents 130 on the main body prosthesis 120. The suture 252 is, in turn, looped around the releasing means 228, e.g., a release wire 250, when the release wire 250 is in its proximal-most position, as Figs. 17 and 18A shows. Distal retraction of the wire 250 withdraws the wire 250 from the suture loop 252, and allows the proximal end 108 of the main body prosthesis 120 to radially expand, as Fig. 19 shows. In an alternative embodiment, the suture 252 may comprise more than one

suture, i.e., two or more suture loops. Fig. 18B shows the path of two suture loops 252 looped around the release wire 250.

Belt loops or the like may be provided on the main body prosthesis 120 and/or lumen extensions 140 to guide and support the suture loop(s) along the path of the suture loop (see Figs. 17 and 46B for example). The belt loops can be spaced at desired circumferential intervals, such as every ninety degrees, for example.

In the illustrated embodiment, one end of the suture loop 252 is coupled to the prosthetic material 112 or one or more stents 130 at or near the proximal end 108 of the main body prosthesis 120. The suture loop 252 is then looped around the main body prosthesis 120 and the releasing means 228 in a predetermined pattern, as shown in Fig. 18A, in order to compress and retain the proximal end 108 of the prosthesis 120. The free end of the suture loop 252 is then coupled to the prosthetic material 112 or one or more stents 130 at or near the proximal end 108 of the main body prosthesis 120. Fig. 18B shows two separate loops 252 looped around the main body prosthesis 120 and the release wire 250. It should be appreciated, however, that suture loop 252 could be coupled to stents elsewhere in the main body prosthesis 120, and/or the other components of the main body prosthesis 120 as well.

The suture loop 252 and releasing means 228, e.g., release wire 250, of the embodiment just described retains the prosthesis 120 in a desired relationship to the central shaft (see Fig. 17). The suture loop 252 and the releasing means 228 help to keep the main body prosthesis 120 from moving distally as the outer jacket 210 is retracted. The suture loop 252 also keeps the stent or stents 130 that are retained by the suture loop 252 in a radially compressed condition as the outer jacket 210 is retracted. The suture loop 252 and releasing means 228 prevent the proximal end 108 of the main body prosthesis 120 from self-expanding until the releasing means 228 has been withdrawn. In the illustrated embodiment, the withdrawal of the releasing means 228 is accomplished by operating a control knob to move the releasing means 228 distally, withdrawing the releasing means 228 away from the suture loop 252. Once the releasing means 228 is

withdrawn, the restrained components of the main body prosthesis 120 are free to self expand, as Fig. 19 shows.

As can be seen in Figs. 20 and 21, the first proximal releasing means 228 comprises a first proximal release hub 244 positioned over the central shaft 216, and a release wire 250. The first proximal release hub 244 may include a small hole or lumen 246 in the proximal end of the hub 244 that is in fluid communication with a first proximal release lumen 248 within the central shaft 216. Each lumen 246, 248 desirably includes a diameter sufficiently large to accommodate the first proximal release wire 250 extending from the handle assembly 212 to beyond the first proximal release hub 244. It is to be appreciated that the release wire 250 may extend external the shaft 216 as well.

The first proximal retaining means 224 holds the main body prosthesis 120 in a desired configuration prior to deployment (see Figs. 17 and 18A) and the first proximal releasing means 228 selectively releases the main body prosthesis 120 for the first stage of deployment (see Fig. 19). In the illustrated embodiment, the distal end of the first proximal release wire 250 is connected to an actuator or control button or knob in the handle assembly 212, as will be described further below.

The main body prosthesis 120 is retained by at least the first proximal retaining means 224 along the central shaft 216 in the cavity 234, which extends between the distal end 242 of the catheter tip component 222 and the proximal end of a spacer 206 (as best seen in Fig. 14A). In the illustrated embodiment, the releasing means 228 includes the release wire 250 that may extend through at least a portion of the central shaft 216. The proximal end of the wire 250 passes through the lumen 246 of the first proximal release hub 244. The first proximal release wire 250 is thereby kept in a desired relationship within or along the central shaft 216. The distal end of the first proximal release wire 250 is coupled to the control knob, such that fore and aft movement of the knob moves the release wire 250, respectively, proximally and distally.

As illustrated and described, the first proximal releasing

means 228 is coupled to one restrained component of the main body prosthesis 120, i.e., suture loop 252. It should be appreciated, however, that the releasing means 228 can be coupled to the main body prosthesis 120 at two or more restrained regions, so that withdrawal of the releasing means 228 frees the prosthesis at two or more restrained regions. It should also be appreciated that the releasing means 228 can comprise more than a single releasing element. For example, multiple, individual releasing wires 250 could be coupled to the main body prosthesis 120 at different regions, so that release of separate regions of the main body prosthesis 120 can be individually controlled.

b. Second Proximal Retaining Means

Referring back to Fig. 12, the proximal retaining means 218 may also incorporate a second retaining means 226 which may function in cooperation with, or separate from the first proximal retaining means 224. The second proximal retaining means 226 may be held in place by the second proximal releasing means 230 in a predetermined, spaced relationship with the central shaft 216.

Referring now to Figs. 22 through 27, the second proximal retaining means 226 may comprise at least one stabilizing arm 256, and/or equivalent structures, and desirably more than one stabilizing arm, such as three stabilizing arms, as shown. The second proximal releasing means 226 may comprise a second proximal release hub 266 and a second proximal release wire or wires 268.

The distal ends 258 of the stabilizing arms 256 are coupled to the second proximal release hub 266. In a pre-deployment configuration, the proximal ends 262 of the stabilizing arms 256 are arched back generally toward the first proximal release hub 244 (see Figs. 23 and 24) and are releasably attached to the prosthesis material 112 at or near the proximal end 108 of the main body prosthesis 120 (see Figs. 24 and 25). In a post-deployment configuration, as seen in Fig. 26, the stabilizing arms 256 extend proximally toward the catheter tip 222.

The proximal ends 262 of the stabilizing arms 256 include a

stabilizing arm aperture 264. In the pre -deployment configuration, the stabilizing arms 256 are positioned within the proximal opening 122 of the main body prosthesis 12 0 and the second proximal release wire 268 is stitched or otherwise extended through the stabilizing arm aperture 264 and through the pr osthesis material 112, releasably securing the stabi lizing arms 256 to the main body prosthesis 120 (as best seen in Fig . 25). Distal r etraction of the second proximal release wire 268 (using a second control knob, to be described later) withdraws the second proximal release wire 268 from the prosthesis material 112 and releases the stab ilizing arms 264. The main body prosthesis 120 is now free from the retentive featu re of the stabilizing arms 256, and the stabilizing arms return to the post - deployment configuration, as show n in Fig. 26. It is to be appreciated that the second proximal release wire 268 may comprise multiple release wires, including one release wire fo r each stabilizing arm 256. The second proximal release wire 268 may comprise a single wire extending through the central shaft, and then divide into multi ple wires to ind ividually engage the stabilizing arms, or the rele ase wire 268 may comprise multiple wires extending through the centra l shaft 216 to in dividually engage each stabilizing arm 256. In an alternative embodiment, the stabilizing arms 256 could be positioned in the reverse orientation on the catheter central shaft 216. Stabilizing arms of this configuration would be biased open away from the central shaft 216 and w ould require a s econdary means to retain them in close proximity to the central shaft 216 in order to b e rejacketed before catheter removal.

In the embodiment shown in Figs. 24 th rough 27, the second proximal retaining means 226 includes a second proximal release hub 266 positioned ov er the central s haft 216. T he second proximal release hub 266 may include a small hole or lumen 270 in the proximal end of the hub 266 that is in flu id communication with the second proximal release l umen 272 within the central shaft (s ee Figs. 24 an d 27). The lumen 270 and 272 desirabl y includes a diameter sufficiently large to accommodate at least one second proximal release wire 268 extending from the handle portion 212 to beyond the second proximal

release hub 266. It is to be appreciated that the release wire 268 may extend external the shaft 216 as well.

The second proximal retaining means 226 holds the main body prosthesis 120 in a desired configuration prior to deployment (see Figs. 19 and 24) and selectively releases the main body prosthesis 120 for the second stage of deployment (see Fig. 26). In the illustrated embodiment, the distal end of the second proximal release wire 268 is connected to an actuator or control button or knob in the handle assembly 212, as will be discussed further below.

The main body prosthesis 120 is retained by the second proximal retaining means 226 in a spaced apart relationship to the central shaft 216 (see Fig. 24). In the illustrated embodiment, the second proximal releasing means 230 includes the second proximal release wire 268 that may extend through at least a portion of the central shaft 216. The proximal end of the release wire 268 passes through the lumen 270 of the second proximal release hub 266. The second proximal release wire 268 is thereby kept in a desired relationship within or along the central shaft 216. The distal end of the second proximal release wire 268 is coupled to the second control knob, such that fore and aft movement of the second knob moves the second proximal release wire 268, respectively, proximally and distally.

iv. Distal Retaining Means

As can be seen in Figs. 28 through 33, in the illustrated embodiment, the distal retaining means 220 comprises at least one suture, or sutures, 274 and/or equivalent structures, which are coupled to the prosthetic material 112, or one or more stents 134 on the main body prosthesis 120. Desirably, the suture 274 is coupled to the prosthesis material 112 near the distal end 110 of the main body 120, and more desirably near the distal opening 127 of the first lumen 126. The suture 274 is, in turn, looped around the releasing means 232, e.g., a release wire 282, when the release wire 282 is in its proximal-most position, as Figs. 28 and 29A show. Distal retraction of the wire 282 withdraws the wire 282 from the suture loop 274, and allows the distal end 110 of the main body prosthesis 120 to radially

expand, as Fig. 30 shows. In an alternative embodiment, the suture 274 may comprise more than one suture, i.e., two or more suture loops. Fig. 29B shows the path of two suture loops 252 looped around the release wire 292.

As described for the first proximal retaining means, belt loops or the like may be provided on the main body prosthesis 120 and/or lumen extensions 140 to guide and support the suture loop(s) along the path of the suture loop. The belt loops can be spaced at desired circumferential intervals, such as every ninety degrees, for example.

In the illustrated embodiment, one end of the suture loop 274 is coupled to the prosthetic material 112 or one or more stents 134 at or near the distal end 110 of the main body prosthesis 120. The suture loop 274 is then looped around the main body prosthesis 120 and the distal releasing means 232 in a predetermined pattern, as shown in Fig. 29A, in order to compress and retain the distal end 110 of the main body prosthesis 120. The free end of the suture loop 274 is then coupled to the prosthetic material 112 or one or more stents 134 at or near the proximal end 110 of the main body prosthesis 120. Fig. 29B shows two separate loops 252 looped around the main body prosthesis 120 and the release wire 250. It should be appreciated, however, that suture loop 274 could be coupled to stents elsewhere in the main body prosthesis 120, and/or the other components of the main body prosthesis 120 as well.

The suture loop 274 and releasing means 232, e.g., release wire 282, of the embodiment just described retain the distal end of the main body prosthesis 120 to the central shaft 216 (see Fig. 28). The suture loop 274 and the releasing means 232 keep the main body prosthesis 120 from moving distally as the outer jacket 210 is retracted. The releasing means 232 also keeps the stent or stents 134 that are retained by the suture loops 274 in a radially compressed condition as the outer jacket 210 is retracted. The suture loop 274 and releasing means 232 prevent the distal end 110 of the main body prosthesis 120 from self-expanding until the releasing means 232 has been withdrawn. In the illustrated embodiment, the withdrawal of the

releasing means 232 is accomplished by operating a control knob to move the releasing means 232 distally, withdrawing the releasing means 232 and away from the suture loop 252. Once the releasing means 232 is withdrawn, the restrained components of the main body prosthesis 120 are free to self expand, as Fig. 30 shows.

In the embodiment shown in Figs. 28 through 31, the distal releasing means 232 includes a distal release hub 276 positioned over the central shaft 216 and a release wire 282. The distal release hub may include a small hole or lumen 278 in the proximal end of the hub that is in fluid communication with a distal release lumen 280 within the central shaft 216 (see Fig. 31). Each lumen 278, 280 desirably includes a diameter sufficiently large to accommodate a distal release wire 282 extending from the handle assembly 212 to beyond the distal release hub. It is to be appreciated that the release wire 282 may extend external to the shaft 216 as well.

The distal retaining means 220 holds the distal end 110 of the main body prosthesis 120 in a desired configuration prior to deployment of the distal end (see Fig. 28) and the distal releasing means 232 selectively releases the distal end 110 of the main body prosthesis 120 for the final stage of deployment (see Fig. 30). In the illustrated embodiment, the distal end of the distal releasing means 232 is connected to an actuator or control button or knob in the handle assembly 212, as will be described further below.

In the illustrated embodiment, the distal releasing means 232 includes the distal release wire 282 that may extend through at least a portion of the central shaft 216. The proximal end of the wire 282 passes through the lumen 278 of the distal release hub 276. The proximal end of the distal release wire 282 then may extend back into the central shaft 216 through the second distal release hole or lumen 284 positioned spaced apart from the distal release hub 276. The proximal end of the release wire 282 is thereby kept in a desired relationship within or along the central shaft 216. The distal end of the distal release wire 282 is coupled to the distal control knob, such that fore and aft movement of the distal control knob moves the distal release wire 282, respectively, distally and proximally.

As illustrated and described, the distal releasing means 232 is coupled to the main body prosthesis 120 or a component of the main body prosthesis, i.e., suture loop 274. It should be appreciated, however, that the distal releasing means 232 can be coupled to the main body prosthesis 120 at two or more restrained regions, so that withdrawal of the distal releasing means 232 frees the prosthesis at two or more restrained regions. It should also be appreciated that the distal releasing means 232 can comprise more than a single releasing element. For example, multiple, individual releasing wires 282 could be coupled to the main body prosthesis 120 at different regions, so that release of separate regions of the distal end of the main body prosthesis 120 can be individually controlled.

In an alternative embodiment, the distal retaining means 220 may comprise the prosthesis material 112. As can be seen in Fig. 32, the distal release wire 282 may be threaded through the prosthesis material 112 near the distal end 110 of the main body prosthesis 120, e.g., the first lumen 126. The distal release wire 282 then desirably extends into the second distal lumen 284. The proximal end of the release wire 282 is thereby kept in a desired relationship within or along the central shaft 216 to retain the wire 282. In this configuration, the distal stent(s) 134 are not radially restrained. As the outer jacket is retracted, the distal end 110 of the main body prosthesis 120 is free to radially expand. The distal release wire 282 serves to maintain the position of the distal end 110 relative to the catheter shaft 216. This feature allows for a greater flow of fluid through the lumens of the main body prosthesis while still maintaining longitudinal or axial control of the main body prosthesis 120 during the deployment process. In the illustrated embodiment, the withdrawal of the release wire 282 is accomplished by operating a control knob to move the release wire 282 distally, withdrawing the release wire 282 from the prosthesis material 112 and releasing the restrained components of the main body prosthesis 120 from the catheter shaft 216, as Fig. 33 shows.

B. The Outer Jacket

As previously described, the outer jacket 210 serves to restrain the stents 130, 134 on the main body prosthesis 120 from expanding and allows for a controlled deployment of the main body prosthesis 120 within the body (see Fig. 14A). In the illustrated arrangement, the outer jacket 210 is coupled to an actuator or knob 302 on the handle assembly 212, as will be described in greater detail below.

As Fig. 14A shows, the outer jacket 210 extends proximally over the spacer 206 and main body prosthesis 120 and terminates adjacent the distal end 242 of the catheter tip component 222. Typically, the outer jacket 210 can be made of a polymer tube or similar materials known in the art. In one embodiment, the jacket 210 may be free of structural reinforcement. In an alternative embodiment (shown in Fig. 14B), the jacket 210 may include structural reinforcement, such as but not limited to, a wire or rod 211 positioned longitudinally along a length of the jacket, and/or a wire or rod 213 positioned helically around a length of the jacket. The structural reinforcement may also be in the form of a coil(s) or braided wire, for example. The plasticity of the structural reinforcement may be altered to affect the flexibility of the jacket 210 depending on a selected application. In addition, the structural reinforcement may extend along the full length of the jacket 210, or may be positioned along only a portion or portions of the length of the jacket. The structural reinforcement may be embedded within the jacket 210, or may be coupled to the interior or exterior surface of the jacket.

In the illustrated embodiment, the outer jacket 210 is configured to maintain a consistent diameter throughout its entire length (see Fig. 11). The outer jacket may also be tapered due to a difference in outer diameters of the catheter tip component 222. The diameter of the outer jacket 210 is intended to contain the main body prosthesis 120, and optionally an extension portion 140 or portions of the main body prosthesis 120, if present. The outer diameter continues distally to the handle assembly 212. The relatively small size of the outer diameter of the outer jacket 210 also allows for better blood

circulation passed the deployment catheter 200.

Returning to Fig. 14A, the spacer 206 provides support for the outer jacket 210 and, by occupying space within the outer jacket 210, reduces the amount of air entrapped within the deployment catheter 200. The proximal end of the spacer 206 desirably terminates adjacent the distal end 110 of the main body prosthesis 120. In this arrangement, the cavity 234 containing the main body prosthesis 120 extends from the distal end 242 of the catheter tip component 222 to the proximal end of the spacer 206. As Fig. 14A shows, the spacer 206 is positioned over the central shaft 216 and the distal end of the spacer 206 is connected to the handle assembly 212. Typically, the spacer 206 can have an outer diameter slightly less than the inner diameter of the outer jacket 210. The spacer 206 can comprise a single lumen or an array of multiple lumens for passage of the various components within the spacer 206.

C. Handle Assembly

The handle assembly 212 provides the operator with longitudinal or axial control and rotational control of the deployment catheter 200 within the body and provides access to the actuator(s) or control means for deploying the main body prosthesis 120.

Referring to Figs. 34 through 36, the handle assembly 212 comprises a handle body 290, a jacket retraction means 292, which is connected to the distal end of the outer jacket 210, a sliding knob 294 which may also be connected to the distal end of the outer jacket 210, and at least one actuator or knob which is attached to the distal end of the proximal and distal releasing means. Desirably, the handle 212 comprises a separate knob for each of the first proximal releasing means 228, the second proximal releasing means 230, and the distal releasing means 232.

In the illustrated embodiment, the central shaft 216 is captured within the handle 212 and has a guide wire receiving luer 296 and an infusion valve 297 coupled to its distal end, which is located at the distal end of the handle assembly 212 (see Figs. 37 and 38). This feature prevents the position of the main body prosthesis 120 from moving relative to the handle body 212 while the outer jacket 210

is retracted, and allows for irrigation or flushing of the catheter shaft 216, such as with a saline solution.

To withdraw the outer jacket 210 from the catheter tip 222 and expose the proximal end of the main body prosthesis 120 (see Figs. 37 through 40), the jacket retraction means 292 is used. The jacket retraction means 292 may include a variety of different mechanisms to selectively control the retraction of the jacket 210 from the catheter tip 222. In the illustrated embodiment, the jacket retraction means 292 comprises a rack and pinion type control mechanism to provide a mechanical advantage sufficient to withdraw the jacket 210 from the catheter tip 222. A pinion 298 is carried by a gear axle 300, and is rotated by a starting knob 302 positioned on at least one end of the gear axle 300, as best seen in Fig. 41. A single starting knob may be present, or as shown in Figs. 39 and 40, two co-acting starting knobs 302 may be available for the clinician, one positioned on a first side 304 and one positioned on a second side 306 of the handle 212. A complimentary rack 308 is carried by a jacket slide 310. The pinion 298 controls distal movement of the rack 308 along the jacket slide 310 between a first (jacket extended) position 312, shown in Fig. 39, and a second (jacket retracted) position 314, shown in Fig. 40.

The jacket slide 310 is coupled to the jacket 210 and is temporarily coupled to the gear rack 308 via a spring loaded connecting pin 316. The connecting pin 316 disengages the jacket slide 310 at a predetermined position in the handle body 290 by springing or otherwise retracting into a recess 318 in the handle body 290. When the connecting pin 316 disengages, the jacket slide 310 is free to travel in both a proximal and distal direction without re-engaging the rack 308. The rack 308 desirably remains in this retracted position 314. A ratchet pawl, such as a spring backed ratchet pawl 320 may be coupled to the rack 308 to allow the rack to travel in a distal direction, but restrict proximal travel of the rack 308. Ratchet teeth 322 may be provided in the handle body 290 to engage the ratchet pawl 320.

Once the jacket slide 310 has traveled distally and the rack 308 has been disengaged, the jacket sliding knob 294 may then be

used to continue the retraction of the jacket 210 from the main body prosthesis 120. The jacket slide 310 is moved distally until the outer jacket 210 is free of the main body prosthesis 120 (see Fig. 60, for example). The portion or portions of the main body prosthesis 120 that are not coupled to the proximal and distal retaining means 218, 220, are free to self-expand, as Fig. 60 shows. However, the portions of the main body prosthesis 120 that are coupled to the proximal and distal retaining means 218, 220, are still restrained from self-expansion, despite withdrawal of the outer jacket 210, as Fig. 60 also shows. The stent structure of the main body prosthesis 120 is thereby kept restrained in a close relationship against the central shaft 216 while the outer jacket 210 is retracted. The proximal and distal retaining means 218, 220 prevents the main body prosthesis 120 from moving relative to the central shaft 216 during retraction of the outer jacket 210, which potentially minimizes blood flow through the main body prosthesis 120 during the deployment process. Furthermore, as described, the main body prosthesis 120 is not "pushed out" of the catheter. The main body prosthesis 120 therefore need not have longitudinal stiffness or a stent structure with a "spine".

To employ the first proximal retaining means 224, the first proximal sliding knob 322 (see Fig. 34) is moved distally until the proximal end of the first proximal releasing means 228 is withdrawn from the first proximal retaining means 224, as previously described. In the illustrated embodiment, the first proximal release wire 250 is positioned within the loops of the suture loop 252, as seen in Figs. 17 and 18A. As the first proximal release wire 250 is withdrawn from the suture loop 252, the suture loop 252 releases its retentive feature, yet may remain coupled to the prosthesis material 112. The proximal end 108 of the main body prosthesis 120 is thereby free to self-expand to its first stage deployment configuration, as Fig. 19 shows.

The same process is repeated for the second proximal retaining means 226 and the distal retaining means 220. To employ the second proximal retaining means 226, the second proximal sliding knob 324 (see Fig. 35) is moved distally until the proximal end of the

second proximal r eleasing means 23 0 is withdrawn f rom the second proximal retaining means 226, as p reviously described. The proximal end 108 of the ma in body prosthesi s 120 is thereby finally released from the catheter shaft 216, as Fig. 26 shows. To employ the distal retaining means 2 20, the distal s liding knob 326 (see Fig. 35) i s moved distally un til the proximal end of the di stal releasing means 232 is withdrawn from the distal r etaining means 220 . The distal en d 110 of the main b ody prosthesis 120 is thereby free to self-expand to its final deploym ent configuration, as Fig. 30 shows . Each of the se steps will be des cribed in greater detail in sectio n V. It is to be appreciated that the sliding buttons or knobs may all be positioned on the first side 304 of the handle, or all may be positioned on the second side 306 o f the handle, or may be positioned with one or more on the first side 304 and one or more on the secon d sid e 306, as shown. It should also be appreciated that the knobs 322, 324, 326, can comprise separate components that are not part of the handle assembly 212, i.e., on the outer jacket 210.

The proximal and distal retaining means 218, 220, desirably cooperate with a release system 328 positioned wi thin the handle housing 290 (see Figs. 37 and 38). Each sliding kn ob 322, 324, 326, is coupled to a release slide 330, 332, 334, respecti vely, positioned within a track 3 36, 338, 340, re spectively, in or on the re lease system 328 (see F igs. 41 through 4 3). Each release slide is coupled to the distal end of the releasing means, such as a re lease wire. It is to be apprecia ted that the rele ase system 328 ma y also include an interlock system, such as a mechanical lin kage for controlling the order by which th e slides may be moved. In additi on, an interlock system could als o include a me chanical linkage to the jacket retraction slide 310. This fe ature would prevent t he activation of the release slid es until the ja cket had been r etracted to a predetermined position. It is also to be appreciated that the sliding knobs may include a symbol to indicate to the clinician an appropriate order of deployment.

As described, the main body prosth esis 120 is not r eleased immediately from proximal end to distal end as th e jacket 210 i s

withdrawn. The proximal and distal stent or stents 130, 134, are released in a secondary operation, which follows the withdrawal of the outer jacket 210. Placement of th e prosthesis exte nsions 140 ca n therefore comprise a next step in the deployment process.

2. Lumen Extension Deployment Catheter

After the main body of the prosthesis 120 has been partially or completely deployed, a lumen extension 140, or lumen extensions, are next to be impl anted. An exte nsion deployment catheter 350 is s hown in Fig. 44. It is to be appr eciated that the extension deployment catheter 350 may incorporate all the feature s disclosed in the description of the deployment ca theter 200. The extension catheter is used fo r deli very and deployme nt of the lum en extensions 140 to the targeted site.

In the illustrate d embodiment, the extension cathet er 350 carries the lumen extension 140 in a radially reduced configuration to the targeted site. At the targeted site, the exte nsion catheter 350 releases the rad ially reduced lu men extension 14 0, which expands radially, and is coupled to a lume n of the main bod y prosthesis 120, as will be described further in section V.

As shown in Figs. 44 through 45B, the extension ca theter 350 comprises an inner assembly 358, an outer jacket 3 60, and a handle assembly 362. These components will now be individu ally described in greater detail.

A. The Inner Assembly

In the illustrate d embodiment (see Fig. 45A), the inner assembly 358 comprises a central shaft 364, which functions as a carrier for the lumen extension 140, proximal retaining means 366, and an extension catheter tip component 368. The proximal retaining means 366 desirably retains at least a por tion of the lumen extension 140 in a radially compressed or partially radially expanded condition prior to deployment and prior to couplin g to the main body prosthesis 120. The proximal retaining means 366 a lso desirably includes a co -acting releasing means or mechanism 370 for maintaining the proximal retaining means 366 in a desired relationship with the lumen extension 140 prior to activation.

In an alternative embodiment (see Fig. 45B), the inner assembly may also include distal retaining means 367. The distal retaining means 367 desirably retains at least the distal portion of the lumen extension 140 in a radially compressed or partially radially expanded condition prior to deployment and prior to coupling to the main body prosthesis 120. The distal retaining means 367 also desirably includes a co-acting releasing means or mechanism 371 for maintaining the distal retaining means 367 in a desired relationship with the lumen extension 140 prior to activation.

i. The Central Shaft

In the embodiments shown in Fig. 45A and 45B, the central shaft 364 and the proximal and distal retaining means 366, 367 are located within the confines of the outer jacket 360. In this respect, the outer jacket 360 functions as an enclosure or jacket for the lumen extension 140 on the shaft 364 (see Figs. 46A and B). In this arrangement, the catheter tip component 368 is attached to the proximal end of the central shaft 364, and the proximal end of the outer jacket 360 terminates adjacent the catheter tip component 368. Thus, the extension catheter tip component 368 extends outward beyond the outer jacket 360. The central shaft 364, the proximal releasing means 366, the distal releasing means 367 (shown in Fig. 45B), and the outer jacket 360 are coupled to the handle assembly 362 at the proximal end of the catheter handle assembly 362 (see Fig. 44). As can be seen in Fig. 46A and 46B, the lumen extension 140 is contained in a cavity 372 defined between the central shaft 364 and the outer jacket 360 in the proximal section of the extension catheter 350.

The central shaft 364 extends from the handle assembly 362 to the catheter tip component 368. The central shaft 364 may be made, e.g., from stainless steel or other suitable medical materials including other metals or polymers. The central shaft 364 comprises at least one lumen, and may comprise more than one lumen.

One lumen may be described as the central lumen 374 (see Fig. 47A and 47B), with an inner diameter between .010 and .120 inches, desirably between .020 and .060 inches and most desirably between .030 and .050 inches. As described, the central lumen 374

allows for the in sertion of a guid e wire, i.e., the first guide wire 30 or the second guide wire 40, up to 0.038" diameter, for example. The catheter tip component 368, havi ng the same features as de scribed for the catheter tip 222 of th e deployment cat heter 200, also desirably has at least one lumen 376 (see Fig. 4 5A) configured to align with at least one lumen within the central shaft 364. This lumen 376 allows for th e insertion of th e guide wire th rough the centra l shaft 364 and t hrough the exten sion catheter tip component 368. Typically this lumen 376 will have an inner diameter between .010 and .120 inches, desirably between .020 and .060 inches and most desirably between .030 and .050 inches.

ii. Proximal Retaining Means

The proximal retaining means 366 and the proximal releasing means 370 may function in the same o r similar fashion as the retaining means 224, 226, and the releasing means 228, 230 embodied in the deployment catheter 200, as pre viously shown and descr ibed. As can be seen in Figs. 46A and 48A, in the illustrated embodiment, the proximal retaining means 366 comprises at least one suture, or sutures, 378 and/or equivalent structures, which are coupled to the lumen extension prosthetic materia l 112, or to one or more s tents 150 on the lumen extension 140. The suture 378 is, i n turn, looped aro und the proximal releasing means 37 0, e.g., a releas e wire 380, when the release wire 380 is in its pr oximal-most position, as Figs. 46 A and 48 A show. Distal retraction of the wire 380 positioned within a releasing wire lumen 381 (see Figs. 45A and 47A) withdraws the wire 380 from the suture loop 378, and allows the proximal end 1 42 of the lume n extension 140 to radially expand, a s can be seen i n Figs. 70 and 71. In an alternative embodiment, the suture 378 may co mprise more than one suture, i.e., two or more sutu re loops. Fig. 4 8C shows the path of two suture loops 378 looped around the release wire 380.

As described for the main body pro sthesis 120, belt loops or the like may b e provided on the lumen extensions 140 as well to guide and support the suture loop (s) along the pa th of the sutur e loop. The belt loops can be sp aced at desired circumferential intervals, such as every ninety degrees, for example.

As can be seen in Fig. 45A, the proximal releasing means 370 comprises a proximal release hub 397 positioned over the central shaft 364, and the release wire 380. The proximal rel ease hub 397 may include a small h ole or lumen 398 in the prox imal e nd of the hub 397 that is in fl uid communication with the proximal releasing wire lumen 381 within the c entral shaft 364. Each lumen 381 , 398 desirably include a diameter sufficiently larg e to accommodate the release wire 380 extending from the hand le assembly 362 to beyond the release hu b 397. It is to b e appreciated that the release wir e 380 may extend external the shaft 364 as well.

iii. Distal Retaining Means

In an alternative embodiment, the distal retaining means 367 and the dista l releasin g means 371 may f unction in the sa me or similar fashion a s the retaining m eans 220, and the releasing means 232 embodied in the deployment catheter 200, as previously shown and described. As can be seen in Figs. 46B and 48B, the distal retaining means 367 comprises at least one suture, or sutures, 379 and/or equivalent struct ures, which are coupled to the lumen extension prosthetic materia l 112, or to one or more s tents 150 on the lumen extension 140. Th e suture 379 is, in turn, looped a round the distal releasing means 37 1, e.g., a releas e wire 383, when the release wire 383 is in its pr oximal-most position, as Figs. 46 B and 48B show . Distal retraction of the wire 383 positioned within a releasing wire lumen 385 (see Fi gs. 45B 47B) with draws the wire 38 3 f rom the suture loop 379, and allows the distal end 144 of the lumen extension 140 to radially expand. As described for the proximal retaining means 366, the suture 379 may also comprise more than one suture, i.e., two or more suture loops. Fig. 48C shows the path of two s uture loops 378 looped around the release wire 380 . This path may also be used fo r suture loops 379 looped around the release wire 383.

As can be seen in Fig. 45B, the distal releasing means 371 comprises a distal release hub 399 positi oned over the central shaft 364, and the release wire 383. The distal release hub 399 may include a small hole or l umen 395 in the p roximal end of the hub 399 that i s in fluid communication with the distal releasing wire lumen 385 within

the central shaft 364. Each lumen 385, 395 desirably include a diameter sufficiently large to accommodate the release wire 383 extending from the handle assembly 362 to beyond the release hub 399. It is to be appreciated that the release wire 383 may extend external the shaft 364 as well.

B. The Outer Jacket

The outer jacket 360 may function in the same or similar fashion as described for the outer jacket 210 embodied in the deployment catheter 200. The outer jacket 360 also serves to restrain the stents 146 and 150 on the lumen extension 140 from expanding and allows for a controlled deployment of the lumen extension 140 within a lumen of the main body prosthesis 120. In the illustrated arrangement, the outer jacket 360 is coupled to an actuator or knob 382 on the handle assembly 362, as will be described in greater detail below.

As Figs. 46A and 46B show, the outer jacket 360 extends proximally over a spacer 384 and lumen extension 140 and terminates adjacent the distal end of the catheter tip component 368. Typically, the outer jacket 360 can be made of a polymer tube or similar materials known in the art. In one embodiment, the jacket 360 may be free of structural reinforcement. In an alternative embodiment (shown in Fig. 46C), the jacket 360 may include structural reinforcement, such as but not limited to, a wire or rod 361 positioned longitudinally along a length of the jacket, and/or a wire or rod 363 positioned helically around a length of the jacket. The structural reinforcement may also be in the form of a coil(s) or braided wire, for example. The plasticity of the structural reinforcement may be altered to affect the flexibility of the jacket 360 depending on a selected application. In addition, the structural reinforcement may extend along the full length of the jacket 360, or may be positioned along only a portion or portions of the length of the jacket. The structural reinforcement may be embedded within the jacket 360, or may be coupled to the interior or exterior surface of the jacket.

If desired, and as shown in Fig. 44B, a stationary outer jacket 365 may be provided that extends from the proximal end of the handle assembly 362. The jacket 360 slides within the stationary

jacket 365. The stationary jacket 365 provides a seal interface with a hemostatic valve at the access site. The stationary jacket 365 can be made of a suitable medical grade plastic, such as Fluroinated Ethylene Propylene (FEP) as non-limiting example. The stationary outer jacket 365 provides column strength and lubricity to reduce friction during sliding actuation of the jacket 360. The stationary outer jacket 365 may also be provided for the prosthesis deployment catheter 200 for the same purposes.

C. Handle Assembly

The handle assembly 362 may function in the same or similar fashion as described for the handle assembly 212 embodied in the deployment catheter 200. The handle assembly 362 provides the operator with longitudinal or axial control and rotational control of the extension deployment catheter 350 within the body and provides access to the actuator(s) or control means for deploying the lumen extension 140.

Referring to Figs. 49 and 50, the handle assembly 362 comprises a handle body 386, a jacket retraction means 382, which is connected to the distal end of the outer jacket 360, and at least one knob or button 392 which is attached to the distal end of the proximal releasing means 370. It is to be appreciated that the handle assembly 362 may also include at least one knob or button 393 (see Fig. 49B) attached to an optional distal releasing means 371 and the knob or button may function in the same or similar fashion as described below for the proximal releasing means 370.

In the illustrated embodiment, the central shaft 364 is captured within the handle 362 and has a guide wire receiving luer 388 and an infusion valve 390 coupled to its distal end, which is located at the distal end of the handle assembly 362 (see Figs. 50 and 51). This feature prevents the position of the lumen extension 140 from moving relative to the handle body 362 while the outer jacket 360 is retracted, and allows for irrigation or flushing of the catheter shaft 364, such as with a saline solution.

To withdraw the outer jacket 360 from the catheter tip 368 and expose the lumen extension 140, jacket retraction means, such as

the jacket retraction knob 382 may be used. The jacket retraction means 382 may include a variety of different mechanisms to selectively control the retraction of the jacket 360 from the catheter tip 368. In the illustrated embodiment, the jacket retraction means comprises two co-acting retraction knobs 382 which are available for the clinician, one positioned on each side of the handle 362.

The jacket retraction knob 382 is used to retract the jacket 360 from the lumen extension 140. The jacket retraction knob 382 is moved distally until the outer jacket 360 is free of the lumen extension 140 (see Fig. 70). The portion or portions of the lumen extension 140 that are not coupled to the proximal retaining means 366 are free to self-expand, as Fig. 70 shows. However, the portions of the lumen extension 140 that are coupled to the proximal retaining means 366 are still restrained from self-expansion, despite withdrawal of the outer jacket 360. The stent structure of the lumen extension 140 is thereby kept restrained in a close relationship against the central shaft 364 while the outer jacket 360 is retracted. The proximal retaining means 366 prevents the lumen extension 140 from moving relative to the central shaft 364 during retraction of the outer jacket 360, which potentially minimizes blood flow through the lumen extension 140 during the deployment process. Furthermore, as described, the lumen extension 140 is not "pushed out" of the extension catheter 350. The lumen extension 140 therefore need not have longitudinal stiffness or a stent structure with a "spine".

To employ the proximal retaining means 366, the proximal release sliding knob 392 (see Figs. 49A and 50) is moved distally until the proximal end of the proximal releasing means 370 is withdrawn from the proximal retaining means 366, as previously described. In the illustrated embodiment, the proximal release wire 380 is positioned within the loops of the suture loop 378, as seen in Figs. 46A and 48A. As the proximal release wire 380 is withdrawn from the suture loop 378, the suture loop 378 releases its retentive feature, yet may remain coupled to the prosthesis material 112. The proximal end 142 of the lumen extension 140 is thereby free to self-expand to its deployment configuration and couple itself within the

lumen of the main body prosthesis 120, as Figs. 70 and 71 show. The natural flow of fluid through the new extension 140 provides sufficient force to cause the restraint mechanism of the lumen extension 140 to engage the co-acting restraint mechanism of the main body prosthesis 120. The lumen extension stent and/or the outwardly extending apices 147 of the lumen extension stent 150 engage the mating outwardly extending apices 136 of the main body prosthesis stent 134 (see Fig. 10B). Each of these steps will be described in greater detail in section V. It is to be appreciated that the sliding buttons or knobs may all be positioned on one side of the handle, or all may be positioned on the opposite side of the handle, or may be positioned on both sides, as shown. It should also be appreciated that the knobs 382 and 392 can comprise separate components that are not part of the handle assembly 362, i.e., on the outer jacket 360.

The proximal retaining means 366 desirably cooperate with a release system 394 positioned within the handle housing 386. Proximal release sliding knob 392 is coupled to a release slide 396 positioned within a track 398 in or on the release system 394 (see Fig. 51). The release slide 396 is coupled to the distal end of the releasing means 370, such as the release wire 380. It is to be appreciated that the release system 394 may also include an interlock system, such as a mechanical linkage for controlling the order by which the slides may be moved. In addition, an interlock system could also include a mechanical linkage to the jacket retraction slide 382. This feature would prevent the activation of the release slides until the jacket had been retracted to a predetermined position. It is also to be appreciated that the sliding knobs may include a symbol to indicate to the clinician an appropriate order of deployment.

As described, the lumen extension 140 is not released immediately from proximal end to distal end as the jacket 360 is withdrawn. The lumen extension stent or stents 146 and 150 may be released in a secondary operation, which follows the withdrawal of the outer jacket 360. Placement of the prosthesis extensions 140 can therefore comprise a final step in the deployment process.

3. Fastener Device And Fastener

As previously described, one or more fasteners 402 (see Fig. 52) may be introduced by a fastener device 400 to anchor the prosthesis 100 in place. Typically the fasteners 402 will be introduced at the proximal end of the main body prosthesis 120; however, it should be appreciated that the fasteners can be introduced in any part of the prosthesis 100, including the lumen extensions 140, to anchor it in place. In addition, the fasteners 402 may also serve to provide apposition of the prosthesis material 112 to the hollow body organ or vessel wall. Fasteners may also be used to seal and/or repair leaks or seepage of fluid (e.g., around the proximal stents and/or distal stents of the prosthesis 100). One or more fasteners 402 may be introduced into the prosthesis 100 at different times or at the same time during the procedure.

As can be seen in Figs. 53 and 54, the fastener tool 400 desirably comprises a handle assembly 404 including a control assembly 406 and an indication assembly 408. A fastener delivery shaft 409, having a fastener driver 411 at its proximal end 410, is coupled to the proximal end of the handle assembly 404 for delivery of the fastener 402. Coupled to the distal end of the handle assembly may be an irrigation port or infusion valve 422.

The handle assembly 404 provides the fastening control feature for the clinician. Positioned within the handle assembly 404 is the control assembly 406. The control assembly provides motion control, such as a forward and reverse drive feature, for turning or otherwise moving the fastener 402 to or from a fastening position. The control assembly desirably includes a forward control button 412 and a reverse control button 414. The forward and reverse control buttons 412, 414 provide the clinician an ergonomic and single finger control of the fastener device 400.

The handle assembly desirably includes an indication assembly 408 to provide control information to the clinician. The indication assembly may include indication lights, i.e., LEDs, and/or the ability to produce audible signals (tones) to provide visual and/or audible indication of forward or reverse movement of the fastener 402, for example, by way of a variety of tones and/or a

forward light 41 6 and a rev erse light 418. A dditionally, the indication assembly may include status tones and/or a status light 420 to provide a varie ty of information back to the clinic ian. The tones may use a variety of pitches or pulses, for example, and the status light 420 may u se a variety a flas h signals and ill umination times, for example, to provide these different indications fo r the clinician, such as error indication, position indication, and timing indication, for example.

Further details of the fastener device 400 and fastener 402 can be found i n United States Patent Application Serial No. 10/307,226, filed November 29, 2002, and entitled "Intraluminal Prosthesis Attachment Systems and Methods," and in U.S. Patent Application Serial No. 10/786,465 , filed February 29, 20 04 and entitled "Systems and Methods for Attaching a Prosthesis Within a Body Lumen or Hollow Organ, " which are both incorpo rated herein by reference.

In this embodimen t, the proximal c oil 422 of the fa stener 402 is formed to produce a diago nal member 424 , which crosses th e diameter of the h elical fastener. T he distal end of the fastener 402 comprises a sharp ened tip 426, suc h as a con ical t ip or a ch iseled tip, for example, to aid in the ea se of tissue pene tration. Similar helical fasteners are described in U.S. Patent No. 5,964,772; 5,824,008; 5,582,616; and 6,296,656, the full disclosures of which are incorporated herein by reference.

In an alternative embodiment, the fastener device 400 and a fastener 430 may comprise features allowing the fastener 43 0 to be releasably secured to the fastener driver 432. As can be seen in Figs. 79A and 79B , the proximal co il 434 of the hel ical fastener 430 desirably includes a diagonal membe r 436, which cros ses the diameter of the fastener 43 0. The diagonal member 436 may bis ect the diameter of the fastener 4 30, or may be off set, forming a "D " shaped proximal coil 434, as shown. The diagonal member 436 desirably comes completely across the diameter to prevent the fastener 430 from bein g an open coil and to control th e depth of penetration into the tissue. In addition, the diagonal member 436 can be attache d to a previou s

coil, as shown, to strengthen the entire structure and provide a retentive shape for a fastener driver 432. This attachment could be achieved via welding, adhesive or any other suitable means.

Located at the proximal end of the fastener delivery shaft 410 is the fastener driver 432. In the illustrated embodiment (see Figs. 80 and 81), the fastener driver 432 includes a fastener carrier 438 positioned within a threaded fastener housing 439. The threaded fastener housing 439 may include tabs 437 or other coupling means so as to snap fit or couple to the fastener carrier 438 for convenient replacement. The coupling between the driver 432 and carrier 438 can take different forms - e.g., magnets, graspers, or other suitable mechanical connection. In the embodiment illustrated in Figs. 80 and 81, the driver 432 and carrier 438 are integrally connected as a single unit.

The carrier 438 is sized and configured to engage a selected fastener 430. The diagonal member 436 serves to define a shape, such as a "D" shape, to engage the carrier 438, which rotates the fastener 430 positioned over the carrier 438 to achieve fastening the prosthesis to tissue. The diagonal member 436 also serves as a stop to prevent the helical fastener 430 from penetrating too far into the tissue.

As can be seen in Figs. 80 and 81, a fastener 430 is positioned within the fastener housing 439 and over the carrier 438. The carrier 438 includes a release latch 440. The release latch 440 may be spring loaded, magnetic, or lever action, for example. The latch 440 prevents the premature release of the fastener 430. The release latch 440 desirably requires a force to overcome the securing force of the latch. For example, the release latch 440 may be overcome by a pulling force, e.g., the fastener 430 is being fastened through the prosthesis and within tissue and the pulling force of the fastener turning or screwing into tissue may overcome the securing force of the release latch. Alternatively, the release latch 440 may be overcome by a magnetic force activated by the clinician by pressing a release button 444 on the handle assembly 404 (shown in Fig. 86). In one embodiment shown in Figs. 82A and 82B, the release latch 440

includes a lever arm 442 to provide the latching force. As the carrier 438 is rotated to deploy the fastener 430, the force of the fastener 430 rotating into the tissue may be adequate to overcome the force of the release latch 440. As seen in Fig. 82A, the fastener 430 remains fastened to the carrier 438 by way of the fastener release latch 440. As seen in Fig. 82B, further rotation of the fastener 430 into tissue will cause each coil of the fastener to overcome the force of the release latch 440 and allow the fastener 430 to exit off of the carrier 438.

In an alternative embodiment, the release latch 440 may include a release spring 445, as seen in Fig. 82C. The release spring 445 is sized and configured to provide a sufficient force to maintain the fastener 430 on the carrier 438, and yet allow the fastener 430 to overcome the force of the release spring 445 and release latch 440 as the fastener is being screwed into tissue.

The fastener housing 439 desirably includes a predetermined amount of internal threads 441 (e.g., two or three threads). In this configuration, the threaded portion of the housing 439 may not be continuous throughout the length of the housing. The threads 441 engage the fastener 430 when the fastener is being loaded onto the fastener driver 432 (as described below) and also partially drive the helical fastener 430 out of the fastener driver 432 and into tissue. Desirably, the threaded portion of the threaded housing terminates a predetermined distance from the housing tip 443. This unthreaded portion of the threaded housing 439 provides an area in which the fastener 430 can be rotated but not be driven out of the fastener driver 432. This unthreaded feature of the housing 439 allows the fastener 430 to pull itself out of the fastener driver 432 when rotated by the driver only as long as the fastener 430 has been previously engaged with the prosthesis 120 and tissue. This feature ensures a more uniform depth of penetration for the fastener 430.

A helical fastener, such as 402 and 430, for example, may be positioned in a fastener cassette 446, as seen in Figs. 83 and 84. The fastener cassette 446 may take on any convenient shape, such as a rectangle or circle, as shown, and may include any convenient number

of fastener receptacles 448, such as six, although any number may be used. The cassette 446 may be used to store and retain fasteners during shipment, and also to provide a convenient means to present the fastener 430, for example, to the fastener device 400 during a medical procedure.

As seen in Figs. 83 and 84, the fastener receptacle 448 is sized and configured to allow the proximal end 410 and the fastener driver 432 of the fastener device 400 access to the seated fastener 430. The fastener 430 may be positioned on a receptacle post 449, to hold the fastener 430 within the receptacle 448. Or alternately, the fastener 430 may be held within the receptacle 448 through interference between the fastener 430 and the receptacle 448, or by penetrating the fastener tip 426 into a material at the base of the receptacle 448. The receptacle post 449 may include a receptacle post spring 447, allowing the receptacle post 449 to retreat into the receptacle 448 as the fastener driver 432 is inserted into the receptacle 448 to position the fastener 430 on to the carrier 438.

Figs. 85 and 86 show an embodiment of a fastener 430 being positioned within the fastener driver 432. As can be seen the fastener driver 432 is positioned on top of the receptacle 448 and gently inserted into the receptacle. The force of the insertion allows the fastener 430 to overcome the force of the release latch 440 on the carrier 438 and to be positioned over the carrier 438. The fastener driver is then reversed, using the control assembly 406 provided on the fastener driver handle 404. The internal threads 441 of the threaded housing 439 draw the fastener 430 into the fastener driver 432 and into position for deployment. Fig. 86 shows the fastener 430 removed from the cassette 446 and positioned on the fastener driver 432. It is to be appreciated that the cassette 446 can be used to hold a variety of fastener shapes and sizes, and is not limited to the fastener 430, as described.

4. Steerable Guide Device

A steerable guide device 450 may be used to establish an open path through which an operative tool, such as the fastener device 400, can be deployed for use. Figs. 55 and 56 show an embodiment of

the steerable guide device 450. The steerable guide device comprises a flexible guide tube 452 carried by a handle 454. The handle is sized and configured to be ergonomically held by the clinician to introduce the guide tube 452 to the targeted site.

In order to establish an open path for the fastener device 400, the steerable guide device 450 includes an interior guide passage 456 which extends through the interior portion of the handle 454 continuously and into and through the guide tube 452. The distal end of the handle 454 may also include a seal 457 to restrict the flow of fluids through the guide tube 452. During introduction of the guide tube through the vasculature to the targeted site, an obturator or dilator 458 having a tip component 459 (see Fig. 57) is positioned within the guide tube 452 in order to seal the guide tube and restrict the flow of fluids through the guide tube 452, to provide an atraumatic tip for guiding through the vasculature, and to provide a guide wire lumen 470.

The handle assembly desirably includes a rotatable steering assembly 460 and a flushing port 462. The steering assembly 460 is used to deflect the proximal end 464 of the guide tube 452 to a bent or deflected configuration, as will be described later. The steering assembly 460 is rotated in a desired direction, causing the proximal end 464 to bend or deflect in a predetermined configuration. A radiopaque marker 466 can be placed on the proximal end region 464 of the guide tube 452 to allow for fluoroscopic visualization of the orientation of the deflected end region. In the bent or deflected configuration, the proximal end 464 can be oriented in a desired relationship with the targeted site.

Further details of the steerable guide device 450 can be found in United States Patent Application Serial No. No. 11/254,619, filed 20 October 2005, and entitled "Devices, Systems, and Methods for Guiding an Operative Tool Into an Interior Body Region," which is incorporated herein by reference.

V. Detailed Implantation Methods

The generally described steps of implantation of the prosthesis 100 provided in Section II will now be described in greater

detail. In the illustrated embodiment, deployment of the bifurcated prosthesis 100 may generally be achieved in a twelve step process, for example, and is shown generally in Figs. 58 through 78. The exemplary embodiment will describe the systems, methods, and uses of the tools for implanting the prosthesis 100. It is to be understood that these same or similar systems, methods, and tools may be used to implant other prosthesis configurations in other areas of the body as well. Throughout the implantation process, image guidance may be used and in conjunction with radiopaque markers positioned on the prosthesis 100 and deployment tools.

Access to the vascular system is commonly provided through the use of introducers known in the art. A hemostasis introducer sheath (not shown), for example, may be first positioned in the left femoral artery, providing access for the implantation tools. A second introducer sheath (not shown) may also be positioned in the right femoral artery, providing access for the implantation tools. It is to be understood that alternative access points may also be used. Access at both the left femoral artery and the right femoral artery, for example, allows for multiple implantation tools to be positioned within the vasculature at the same time, allowing the implantation procedure to be efficiently performed.

A. Position Main Body Prosthesis

A first step includes positioning the main body prosthesis 120 at the desired location. From either the left or right femoral artery, under image guidance, the first guide wire 30 is advanced into the ipsilateral iliac artery and to the descending aorta. The deployment catheter 200 is then navigated over the first guide wire 30 to the desired location within the body, (e.g., aortic aneurysm), for deployment of the main body prosthesis 120 (as Fig. 58 shows). A conventional hemostatic valve arrangement may be used at the access site (shown for purposes of illustration in Fig. 44B).

B. Retract Outer Jacket

Next, the outer jacket 210 is retracted in a distal or caudal direction to expose the main body prosthesis 120. By first rotating the starting knob 302 on the handle assembly 212, the outer

jacket 210 is initially retracted from its secure position on the catheter tip 222. After the mechanical advantage provided by the rotation of the starting knob 302 has retracted the outer jacket 210 away from the catheter tip 222, the jacket sliding knob 294 on the handle 212 may be used to further retract the jacket 210 and fully expose the main body prosthesis 120 (as Figs. 59 and 60 show). The unrestrained portion or portions of the main body prosthesis 120 self-expand, as can be seen in Fig. 60. Optionally, the first lumen 126 may not be radially restrained, but still restrained in relation to the central shaft 216 (see Fig. 32), so as the outer jacket 210 is retracted, the first lumen 126 may self expand as well, as can be seen in Fig. 61. As Figs. 59 through 61 show, both during and after retraction of the outer jacket 210, the main body prosthesis 120 maintains its position relative to the central shaft 216 due to the proximal and distal retaining means 218, 220, coupled to the main body prosthesis 120.

It should be appreciated that the withdrawal of the outer jacket 210 and the withdrawal of the proximal and distal releasing means 228, 230, 232, or any combination thereof, can be accomplished in a single step or process or in multiple steps. In this arrangement, a single activation mechanism can be jointly coupled to the outer jacket 210 and any or all of the releasing means 228, 230, 232, so that the outer jacket 210 and releasing means 228, 230, 232, are withdrawn in a single step, or multiple steps.

C. Release First Proximal Retaining Means

In the third general step of the deployment process, following the withdrawal of the outer jacket 210, the first proximal sliding knob 322 on the handle assembly 212 is moved distally, which causes the proximal end of the first proximal releasing means 228, i.e., the first proximal release wire 250, to be withdrawn from the first proximal retaining means 224, i.e., the suture loop 252, and allows the restrained stent or stents 130, and the proximal end 108 of the main body prosthesis 120 as a whole, to self-expand radially to the first stage deployment configuration, as seen in Fig. 62. The proximal end 108 of the main body prosthesis 120 desirably radially

expands to contact the internal walls of the vessel or hollow body organ.

D. Fasten Proximal End

The fourth general stage comprises fastening the proximal end 108 of the main body prosthesis 120 to the internal walls of the vessel or hollow body organ. From the right femoral artery, under image guidance, a second guide wire 40 is advanced using a conventional intravascular approach into the contralateral iliac artery and to the descending aorta. However, other access sites and methods can be utilized. The guide wire 40 desirably extends through the second expanded lumen 128 and through the proximal opening 122 of the main body prosthesis 120 (see Fig. 63). Next, the steerable guide device 450, with the obturator 458 positioned within the interior guide passage 456, is then navigated over the second guide wire 40 to the desired location with respect to the main body prosthesis 120 (see Fig. 64). Once the steerable guide device 450 is in position, the obturator 458 and the second guide wire 40 are both removed from the interior guide passage 456 and from the body.

By rotating the steering assembly 460 (see Fig. 55), and still employing fluoroscopy visualization, the clinician deflects the proximal end region 464 - and rotates the handle 454 to rotate the flexible guide tube 452 if necessary - to orient the proximal opening 468 of the passage 456 in a desired facing relationship with the site where introduction of a fastener 402 is desired. An operative tool, such as the fastener device 400 is then inserted through the interior guide passage 456 of the steerable guide device 450, and advanced until a fastener, such as the fastener 402, is located for deployment in relation to the now-oriented proximal opening 468, as Fig. 65 shows. As the fastener device 400 is advanced out of the steerable guide device 450 and contacts the wall of the main body prosthesis 120, a resultant force is applied to the proximal end 464 of the steerable guide 450 which moves in the opposite direction of the fastener device proximal end 410. The resultant force causes the proximal end 464 of the steerable guide 450 to deflect until it contacts the opposite wall of the main body prosthesis within the

lumen or hollow body organ. In this way, the force applied to the main body prosthesis 120 and vascular wall from the proximal end 410 of the fastener device 400 is partially resolved through the steerable guide 450 within the vessel or hollow body organ. A representative embodiment of an endovascular device that, in use, applies a helical fastener is described in U.S. Patent Application No. 10/786,465, filed February 25, 2004, and entitled "Systems and Methods for Attaching a Prosthesis Within a Body Lumen or Hollow Organ," which is incorporated herein by reference.

The fastener device 400 can then be actuated to apply a fastener 402 to the proximal end 108 of the main body prosthesis 120 and into the surrounding tissue (see Fig. 66). If the fastener device 400 is a single fire device, i.e., it carries only one fastener 402, the fastener device 400 is withdrawn through the interior guide passage 456 and a new fastener 402 is mounted. See Figs 85 and 86 for one embodiment of the fastener 430 being mounted to the fastener device 400. The proximal end region 464 of the steerable device 450 is reoriented in facing relationship with a new fastening site. The fastener device 400 is inserted back through the interior guide passage 456 to apply a second fastener 402 to the new fastening site (see Fig. 67). This sequence is repeated until a desired number and array of fasteners 402 are applied to the main body prosthesis 120, as can be seen in Fig. 68.

At this point, the fastener device 400 is withdrawn, leaving the steerable guide device 450 in place. The obturator 458 is repositioned within the interior guide passage 456, and the second guide wire 40 is navigated through the obturator lumen 470 to the desired location with respect to the main body prosthesis 120. Once the second guide wire 40 is in position, the steerable guide device 450 and the obturator 458 are both removed from the interior guide passage 456 and from the body leaving the second guide wire 40 in position within the vasculature.

E. Position First Lumen Extension

In the fifth general stage of the deployment process, following the fastening of the proximal end 108 of the main body

prosthesis 120, the extension deployment catheter 350 is used to position a lumen extension 140 for deployment within a lumen of the main body prosthesis 120. From the left or right femoral artery, under image guidance, the extension catheter 350 is navigated over the second guide wire 40 to the desired location, i.e., telescopically positioned partially within the second lumen 128 of the main body prosthesis 120, as Fig. 69 shows. A conventional hemostatic valve arrangement may be used at the access site (shown for purposes of illustration in Fig. 44B).

F. Retract Extension Catheter Outer Jacket

Next, the extension catheter's outer jacket 360 must be retracted in a distal or caudal direction to expose the lumen extension 140. The jacket sliding knob 382 on the extension catheter handle 362 is urged in a distal direction to retract the jacket 360 and fully expose the lumen extension 140. The unrestrained portion or portions of the lumen extension 140 self-expand (see Fig. 70). Both during and after retraction of the outer jacket 360, the lumen extension 140 maintains its position relative to the central shaft 356 due to the proximal retaining means 366, coupled to the lumen extension 140.

G. Release Lumen Extension Proximal Retaining Means

In the seventh general step of the deployment process, following the withdrawal of the extension catheter outer jacket 360, the proximal sliding knob 382 on the extension catheter handle assembly 362 is moved distally, which causes the proximal end of the proximal releasing means 370, i.e., the proximal release wire 380, to be withdrawn from the proximal retaining means 366, i.e., the suture loop 378, and allows the restrained stent or stents 150, and the proximal end 142 of the lumen extension 140, to self-expand radially to the deployment configuration, as seen in Figs. 70 and 71. The proximal end 142 of the lumen extension 140 desirably enlarges to contact the internal walls of the second lumen 128 of the main body prosthesis 140. The natural flow of fluid through the lumen extension 140 provides sufficient force to cause the restraint mechanism of the lumen extension 140 to engage the co-acting restraint mechanism of the

main body prosthesis 120. The lumen extension stent and/or outwardly extending apices 147 of the lumen extension stent 150 engage the mating outwardly extending apices 136 of the distal stent 134 positioned within the second lumen 128 of the main body prosthesis 120 (as best seen in Fig. 10B) in order to couple the lumen extension 140 to the main body prosthesis 120.

Prior to withdrawing the extension catheter 350, the outer jacket 360 is desirably repositioned in an abutting relationship with the catheter tip 368. The jacket sliding knob 382 on the extension catheter handle 362 is urged in a proximal direction to reposition the jacket 360 in a pre-deployment configuration. The extension catheter 350 may now be withdrawn and removed from the body. The second guide wire 40 may either be removed, or may remain until the deployment process is completed.

H. Release Second Proximal Retaining Means

In the eighth general stage of the deployment process, following the deployment of a first lumen extension 140, the second proximal retaining means 226 is released. To release the proximal end 108 of the main body prosthesis 120, the second proximal release sliding knob 324 on the handle 212 is moved distally, which causes the proximal end of the second proximal releasing means 230, i.e., the second proximal release wire 268, to be withdrawn from the prosthesis material 112 and the stabilizing arm apertures 264, and allows the stabilizing arms 256 to release from the proximal end 108 of the main body prosthesis 120, and spring proximally, as shown in Fig. 72. The proximal end 108 of the main body prosthesis 120 is no longer in a restrained relationship with the central shaft 216.

I. Release Distal Retaining Means

In the ninth general stage of the deployment process, following the release of the second proximal retaining means 226, the distal retaining means 220 is released. To release the distal end 110 of the main body prosthesis 140, the distal release sliding knob 326 on the handle 212 is moved distally, which causes the proximal end of the distal releasing means 232, i.e., the distal release wire 282, to be withdrawn from the distal retaining means 220, i.e., the distal

suture loop 274, and allows the restrained stent or stents 134 to self-expand radially to the second stage deployment configuration, as seen in Fig. 73. As previously mentioned, alternatively, the stent or stents 140 are not necessarily radially restrained by the distal retaining means 226. The main body prosthesis 120 is no longer in a restrained relationship with the central shaft 216.

Prior to withdrawing the deployment catheter 200, the outer jacket 210 is desirably repositioned in an abutting relationship with the catheter tip 222. The jacket sliding knob 294 on the catheter handle 212 is urged in a proximal direction to reposition the jacket 210 in a pre-deployment configuration. The deployment catheter 200 may now be withdrawn from the body, leaving the first guide wire 30 within the vasculature (see Fig. 74).

J. Position Second Lumen Extension

In the tenth general stage of the deployment process, following the release of the distal retaining means 220 and withdrawal of the deployment catheter 200, the second lumen extension 140 is positioned for deployment. The general steps as described for the deployment of the first lumen extension 140 are the same or similar, but will be repeated here for clarity. The extension deployment catheter 350 is again used to position the second lumen extension 140 for deployment within a lumen of the main body prosthesis 120. From the left or right femoral artery, for example, under image guidance, the extension catheter 350 is navigated over the first guide wire 30 to the desired location, i.e., telescopically positioned partially within the first lumen 126 of the main body prosthesis 120, as Fig. 75 shows. Again, as previously described, a conventional hemostatic valve arrangement may be used at the access site (shown for purposes of illustration in Fig. 44B).

K. Retract Extension Catheter Outer Jacket

Next, the extension catheter's outer jacket 360 must be retracted in a distal or caudal direction to expose the lumen extension 140. The jacket sliding knob 382 on the extension catheter handle 362 is urged in a distal direction to retract the jacket 360 and fully expose the lumen extension 140. The unrestrained portion or

portions of the lumen extension 140 self-expand (see Figs. 75 and 76). As Fig. 76 shows, both during and after retraction of the outer jacket 360, the lumen extension 140 maintains its position relative to the central shaft 356 due to the proximal retaining means 366, coupled to the lumen extension 140.

L. Release Lumen Extension Proximal Retaining Means

In the twelfth general step of the deployment process, following the withdrawal of the extension catheter outer jacket 360, the proximal sliding knob 382 on the extension catheter handle assembly 362 is moved distally, which causes the proximal end of the proximal releasing means 370, i.e., the proximal release wire 380, to be withdrawn from the proximal retaining means 366, i.e., the suture loop 378, and allows the restrained stent or stents 150, and the proximal end 142 of the lumen extension 140, to self-expand radially to the deployment configuration, as seen in Fig. 77. The proximal end 142 of the lumen extension 140 desirably enlarges to contact the internal walls of the first lumen 126 of the main body prosthesis 140. The natural flow of fluid through the lumen extension 140 provides sufficient force to cause the restraint mechanism of the lumen extension 140 to engage the co-acting restraint mechanism of the main body prosthesis 120. The lumen extension stent and/or the outwardly extending apices 147 of the lumen extension stent 150 engage the mating outwardly extending apices 136 of the distal stent 134 positioned within the first lumen 126 of the main body prosthesis 120 (as best seen in Fig. 10B) in order to couple the lumen extension 140 to the main body prosthesis 120.

Prior to withdrawing the extension catheter 350, the outer jacket 360 is desirably repositioned in an abutting relationship with the catheter tip 368. The jacket sliding knob 382 on the extension catheter handle 362 is urged in a proximal direction to reposition the jacket 360 in a pre-deployment configuration. The extension catheter 350 may now be withdrawn and removed from the body. Both the first guide wire 30 and the second guide wire 40 may now be removed to complete the deployment process of the bifurcated prosthesis 100, as can be seen in Fig. 78.

It is to be appreciated that the general steps just described do not necessarily need to follow the order in which they were described. For example, the second proximal retaining means may be released prior to the deployment of the first lumen extension 140, and the second guide wire may be removed prior to the completion of the deployment process. It is also to be appreciated that fasteners may be applied to the lumen extensions as well to connect the lumen extensions to the iliac arteries.

It will also be appreciated that the components and/or features of the preferred embodiments described herein may be used together or separately, while the depicted methods and devices may be combined or modified in whole or in part. It is contemplated that the components of the guiding device, fastener device, and helical fastener may be alternately oriented relative to each other, for example, offset, bi-axial, etc. Further, it will be understood that the various embodiments may be used in additional procedures not described herein, such as vascular trauma, arterial dissections, artificial heart valve attachment and attachment of other prosthetic device within the vascular system and generally within the body.

The foregoing is considered as illustrative only of the principles of the invention. Furthermore, since numerous modifications and changes will readily occur to those skilled in the art, it is not desired to limit the invention to the exact construction and operation shown and described. While the preferred embodiment has been described, the details may be changed without departing from the invention, which is defined by the claims.

The desired embodiments of the invention are described above in detail for the purpose of setting forth a complete disclosure and for the sake of explanation and clarity. Those skilled in the art will envision other modifications within the scope and spirit of the present disclosure.

I/We Claim:

1. A fastener applier for securing a prosthesis comprising

a handle assembly positioned at t he caudal end of the fastener applier,

a fastener applie r shaft coupled t o the handle assembly, and

a fastener driver for advancing a fastener into the prosthesis and tissue, the fastener driver coupled to the fastener applier shaft at the cephalad end of the fastener a pplier shaft, th e fastener driver including a housing and a release latch, wherein the release latch prevents premature release of th e fastener from the fastener driver.

2. A fastener applier according to claim 1

wherein the fastener driver housing includes an inte rnally threaded portion and a non -threaded portion, the non -threaded portion providing an area where the fasten er can be rotated but not advance d out of the driver, the advancement out of the driver o nly taking place if the fastener has been previously engaged in tissue or the prosthesis.

3. A fastener applier according to claim 1

wherein the handle assembly further inclu des a motion control assembly to be used by an operator, the motion control assembly providing motion control o f the fastener wi thin the fastener driver.

4. A fastener applier according to claim 3

wherein the motion control assembly includes a forward control function and a reverse control function.

5. A fastener applier according to claim 1

wherein the handle assembly further includes an indi cation assembly to prov ide information to an operator, the indication assembly providing at least one of an audible and visual indication.

6. A fastener applier according to claim 5

wherein the information includes at least one of a fastener position or timing or status or error, or any combination.

7. A fastener applier according to claim 1

wherein the fastener is a helical fastener.

8. A fastener applier according to claim 7

wherein the helical fastener includes a fastener body having a distal end for penetrating tissue in response to a force and a proximal end for releasably coupling the fastener body to the fastener applier, and

a stop structure associated with the proximal end to prevent over-penetration of the fastener body into tissue, the stop structure bisecting the diameter of the fastener body.

9. A fastener applier according to claim 8

wherein the stop structure is offset from the diameter of the fastener body.

10. An apparatus for storing a fastener for securing a prosthesis comprising

a base structure, and

at least one receptacle positioned within the base structure, the receptacle sized and configured to releasably store at least one fastener.

11. An apparatus according to claim 10

wherein the receptacle is sized and configured to releasably store at least one helical fastener.

12. An apparatus according to claim 11

wherein the helical fastener includes a fastener body having a distal end for penetrating tissue in response to a force and a proximal end for releasably coupling the fastener body to the fastener applier, and

a stop structure associated with the proximal end to prevent over-penetration of the fastener body into tissue, the stop structure bisecting the diameter of the fastener body.

13. An apparatus according to claim 12

wherein the stop structure is offset from the diameter of the fastener body.

14. An apparatus according to claim 10

wherein the receptacle is sized and configured to present the fastener to a fastener applier.

15. An apparatus according to claim 10

further including a post positioned within the receptacle to releasably restrain the fastener.

16. An apparatus according to claim 10

further including a pliable material within the receptacle to position a tip of the fastener in the pliable material to releasably restrain the fastener.

17. An apparatus according to claim 10

wherein the fastener is releasably restrained within the receptacle by friction between the fastener and the receptacle wall.

Abstract

Devices, systems, and methods for implanting radially expandable prostheses in the body lumens rely on tacking or anchoring the prostheses with separately introduced fasteners. The prosthe ses may be self-expanding or balloon expandable, and may include a single lumen or more than one lumen. After initial placement, a fastener applier system is introduced within the expanded prostheses to deploy a plurality of fasteners to at least one prosthesis end. The fasteners are usually helical fasteners which are releasably restrained on the fastener driver, and are delivered by rotation of the fastener driver. The fasteners may be applied singly, typically in circumferentially spaced-apart patterns about the interior of at least one end of the prosthesis. A lumen extension or lumens may be coupled to the prosthesis to extend the reach of the prosthesis within the implantation site. Fasteners may also be applied to the lumen extensions.